BANCA BT TRANSILVANIA®

SWIFT: BTRLRO22
C.U.I. RO 50 22 670
R.B. - P.J.R. - 12 - 019 - 18.02.1999
Nr. Inreg. Reg. Com.: J12 / 4155 / 1993

Tiparit de STROE DAN IONUT
Tiparit la 30.03.2020

Florina Iustina Ionescu

Digitally signed by Florina Iustina Ionescu
T=Manager, C=RO, S=ARAD, L=ARAD, O=Spitalul Clinic Judetean de Urgenta Arad, OU=Administrativ, E=ionescu.florina@spitalarad.ro, SERIALNUMBER=201104209FII1, G=Florina Iustina, SN=Ionescu, CN=Florina Iustina Ionescu
Certificare autenticitate
Computerul meu
2020.06.03 09:43

Ordin de plata lei

Detalii client

Numar ordin:	35
Nume platitor:	DANSON SRL

Detalii ordin

Cont platitor:	RO08BTRLRONCRT0246370201
Nume beneficiar:	Compania de Asigurari Reasigurari EXIM Romania SA
Banca beneficiar:	BANCA DE EXPORT IMPORT A ROMANIEI
Cont beneficiar:	RO87EXIM101000009935RO01
Suma:	300.00
Detalii plata:	Polita 0024527
Data crearii:	30.03.2020
Referinta tranzactiei:	541EACH200900159
Data tranzactiei:	30.03.2020
Tip transfer:	Normal
Semnatari:	STROE DAN IONUT

SOCIETATEA COMERCIALA I. DANSON S.R.L. - BUCURESTI -

Semnatura platitor

CONFORM CU ORIGINALUL

POLIȚA DE GARANTARE PENTRU LICITAȚII

Seria: GL Număr poliță: 0024527 Data emiterii: 30.03.2020 Cod: 1BF80921

Părți semnatare

ASIGURATOR/ GARANT:	**COMPANIA DE ASIGURĂRI-REASIGURĂRI EXIM ROMANIA S.A. (CARE – ROMANIA).** Sediul social: București, Bulevardul Aviatorilor nr. 33, parter, ap.1, sect. 1, Nr. Reg. Com. J40/3151/2009; CUI: 25252500, prin reprezentant autorizat
ASIGURAT (OFERTANT):	**DANSON SRL**, cu sediul în Bucuresti, Bd-ul Dacia, Nr.81 , Sector 2, Nr. Reg. Com.: J40/23606/1993, CUI: 4781338, reprezentată prin Stroe Marian, în calitate de Administrator
BENEFICIAR (ORGANIZATOR LICITAȚIE)	**Spital Clinic Judetean de Urgenta Arad** cu sediul in Arad, Cod Postal: 310037, Strada: Andreny Karoly, nr. 2-4, CUI: 3519879, Adresa de e-mail: scjuarad.bap@gmail.com, Nr de telefon: +40 357407200, Fax: +40 257211233, Persoana de contact: ANITA RISTA

Elemente de identificare a ofertei: Anunțul de participare nr. SCN1065576/ 20.03.2020

Obiectul ofertei **„Achiziționare echipamente medicale (6 loturi) Lot 2: Aparat de ventilatie mecanica (9 bucati); Lot 5: Ventilator de transport (3 bucati)„**

MENȚIUNI SPECIALE:

Prezenta asigurare de garanție reprezintă un angajament ferm și irevocabil luat de ASIGURATOR, exclusiv pentru anunțul de participare mai sus menționat, privind plata în favoarea BENEFICIARULUI (autorității contractante), a unei despăgubiri, în limita sumei asigurate, necondiționat, respectiv la prima cerere a beneficiarului, pe baza declarației acestuia cu privire la culpa persoanei garantate și fără ca aceasta să aibă obligația de a motiva cererea respectivă, din cauza existentei uneia sau mai multora dintre situațiile următoare:

a) ASIGURATUL (OFERTANT) își retrage oferta în perioada de valabilitate a acesteia;

b) oferta ASIGURATULUI (OFERTANT) fiind stabilită câștigătoare, refuză semnarea contractului în perioada de valabilitate a ofertei;

ASIGURATUL se obliga ferm, **irevocabil și necondiționat** să restituie, la simpla cerere a ASIGURATORULUI, întreaga despăgubire achitată de acesta din urmă BENEFICIARULUI în baza prezentei polițe. în executarea obligației de restituire a despăgubirii achitate, ASIGURATUL nu poate să opună ASIGURATORULUI: culpa BENEFICIARULUI în executarea contractului; litigiile sale cu BENEFICIARUL; diviziunea si/sau discuțiunea indemnizației de asigurare față de BENEFICIAR/ASIGURATOR și nicio altă formă de opoziție întemeiată sau nu, pe care ar putea să o formuleze în baza raporturilor sale legale/contractuale cu BENEFICIARUL.

În vederea garantării restituirii sumei/sumelor plătite de Asigurator Beneficiarului, Asiguratul se oblige sa emită drept garanție o garanție colaterală, pe 100% din Suma asigurată, conform prevederilor Clauzei de garantare.

GARANȚII COLATERALE -

În cazul în care apar neconcordanțe între CONDIȚIILE GENERALE - ASIGURAREA DE GARANȚII CONTRACTUALE, CLAUZA DE GARANTARE PENTRU LICITAȚII, INSTRUMENTUL DE GARANTARE PENTRU PARTICIPARE LA LICITAȚIE și POLIȚA DE ASIGURARE DE GARANTARE PENTRU LICITAȚII , PREVEDERILE POLIȚEI PRIMEAZĂ.

Detalii privind garanția emisă

VALOAREA GARANȚIEI (SUMA ASIGURATĂ)	SUMA: **6.850,00 lei (Lot 2: 5.400,00 lei + Lot 5: 1.450,00 lei)** (sasemiioptsutecincizecilei)
VALABILITATEA GARANȚIEI	Data intrării în vigoare: **31.03.2020** Data expirării: **06.07.2020** Polița intră în vigoare prin plata primei de asigurare de către Asigurat.
PRIMA DE ASIGURARE	**300,00 lei**

Documentele contractului de asigurare

☒ ASIGURAREA DE GARANȚII CONTRACTUALE – CONDIȚII GENERALE;

☒ CLAUZA DE GARANTARE PENTRU LICITAȚII

Această Poliță de asigurare, Condițiile Generale de Asigurare, Clauza de garantare pentru licitații, Instrumentul de garantare pentru licitații și orice alt document semnat individual de către Asigurator și/sau împreună cu Asiguratul și Beneficiarul, fac parte integrantă din Contractul de Asigurare emis de CARE ROMANIA S.A.. Am luat la cunoștință de condițiile Generale de Asigurare și de Clauza de garantare pentru licitații și sunt de acord cu încheierea contractului de asigurare. Declar că informațiile furnizate la încheierea asigurării sunt reale și în conformitate cu datele de care dispun și de asemenea sunt de acord cu folosirea datelor cu caracter personal înscrise în conținutul prezentului document. Prezenta Poliță a fost întocmită în 3 exemplare.

ASIGURAT	AGENT/BROKER	BENEFICIAR	ASIGURĂTOR
DANSON SRL		**Spital Clinic Judetean de Urgenta Arad**	**CARE ROMANIA S.A.**

SOCIETATEA COMERCIALĂ I. DANSON S.R.L. - BUCUREȘTI -

CONFORM CU ORIGINALUL

Vedere de ansamblu

Ordin simplu / Plati interne Romania

Client	Referinta	Executie	Semnaturi	Stare
A0375529	20032612553151	26.03.2020	1	Transmis

Modificari ordin

	Utilizator	Data	Ora
Data inregistrarii	7552902	26.03.2020	12:55
Ultima modificare	7552902	26.03.2020	12:55
1. Semnatura	7552901	26.03.2020	16:24

Ordin

Platitor

Date platitor	CUI/CNP	IBAN platitor
BTL ROMANIA APARATURTA MEDICALA SRL STR. CPT M. VASILESCU, NR. 12-14 BUCURESTI	9731314	RO48RNCB0090000506460001

Detalii

Tip ordin	Suma / Valuta	Numar ordin
Buget	1.450,00 RON	297
Detalii		**NEP / ANAF**
GARANTIE PART LIC LOT NR 5		

Beneficiar

Nume beneficiar		CUI / CNP
SPIT CL JUD DE URG ARAD		3519879
Cont beneficiar	**Nume banca beneficiar**	**Sucursala banca beneficiar**
RO26TREZ0215006XXX016233	MINISTERUL FINANTELOR PUBLICE	ROMANIA

Cod unic de identificare obiect contract: **3519879_2020_PAAPD1135382**

Formularul nr. 7

S C DANSON srl

DECLARAŢIE

privind neîncadrarea în situaţiile de conflict de interese
conform prevederilor art. 60 din Legea 98/2016

Subsemnatul, Dan Ionut Stroe reprezentant legal al S C DANSON srl, în calitate de ofertant la procedura pentru atribuirea contractului de achizitionare echipamente medicale (6 loturi) numar de referinta:3519879_2020_PAAPD1135382 cod CPV 33100000-1 Echipamente medicale (Rev.2) , din data de 30.03.2020, declar pe proprie răspundere, că:

Nu am drept membrii în cadrul consiliului de administraţie/organ de conducere sau de supervizare şi/sau nu am acţionari ori asociaţi persoane care sunt soţ/soţie, rudă sau afin până la gradul al patrulea inclusiv, sau nu mă aflu în relaţii comerciale, astfel cum sunt acestea prevăzute in Legea 98/2016 cu persoanele care deţin funcţii de decizie în cadrul Spitalului Clinic Judetean de Urgenta Arad dupa cum urmeaza:

1	**Duna Flaviu**	Inginer/**Presedinte fara drept de vot Comisie de evaluare**
2	**Voinitchi Alina**	Inginer/**Membru comisie de evaluare**
3	**Buzatu Cerasela**	Medic primar/**Membru comisie de evaluare**
4	**Gulyas Albu Mihaela**	Medic primar/**Membru comisie de evaluare**
5	**Nicolescu Cristian**	Medic primar Sef Sectie ATI/**Membru supleant comisie de evaluare**
6	**Crisan Adrian**	Medic primar/**Membru supleant Comisie de evaluare**
7	**Claudiu Coseri**	Inginer/ **Membru supleant Comisie de evaluare**
8	Carmen Alina Lucuta	Manager
9	Mircea Onel	Director medical
10	Florina Ionescu	Sef Serviciu Financiar Contabil
11	Emilia Otilia Popa	Director ingrijiri medicale
12	Daniel Kurunczi	Director Directia Patrimoniu si Achizitii Publice
13	Simona Virciu	Consilier Juridic
14	Gyorgy Boloni, Petru Mot, Mircea Purcaru, Ioan Gligor, Cornel Lucaci, Adrian Tole, Doru Bozga, Cristian Urzica, Daniel Trifon, Cristian Feies, Florin Remetan, Ciprian Manguci, Simona Stan, Vasile Ciceac, Camelia Craivan, Corina Crisan, Petru Padurean, Cristian Salasan, Ion Ulici, Vasile Mosneag, Adrian Butunoi, Iosif Retter, Gheorghe Sabau, Marius Sulincean, Alin Pop, Daniel Durus, Ioan Plaveti, Garofita Popa, Tamas Carol Pero	Consilieri judeteni
15	Cionca-Arghir Iustin-Marinel	Presedinte Consiliu Judetean Arad
16	Bilcea Ovidiu Sergiu	Vicepresedinte Consiliu Judetean Arad
17	Razvan Olimpiu Cadar	Vicepresedinte Consiliu Judetean Arad
18	Andrei Ando	Director executiv Consiliu Judetean Arad
19	Razvan Ioan Ciubotaru	Director executiv Consiliu Judetean Arad
20	Cristian Cirlugea	Director executiv Consiliu Judetean Arad
21	Gabriela Chiriceu	Director executiv Consiliu Judetean Arad
22	Gheorghina Ribovici	Director executiv Consiliu Judetean Arad
23	Liliana Turjuc	Director executiv adjunct Consiliu Judetean Arad

Subsemnatul declar ca informaţiile furnizate sunt complete şi corecte în fiecare detaliu şi înţeleg ca autoritatea contractantă are dreptul de a solicita, în scopul verificării şi confirmării declaraţiilor, orice documente doveditoare de care dispun.

S.C. DANSON S.R.L. BUCUREŞTI

Cod unic de identificare obiect contract: **3519879_2020_PAAPD1135382**

Înţeleg ca în cazul în care aceasta declaraţie nu este conformă cu realitatea sunt pasibil de încălcarea prevederilor legislaţiei penale privind falsul în declaraţii.

Pentru orice abatere de la prevederile legislative prezentate mai sus, îmi asum răspunderea exclusivă.

Data completării 30.03.2020

S C DANSON srl,
Director General,
Dan Ionut Stroe,
.....

Cod unic de identificare obiect contract: **3519879_2020_PAAPD1135382**

S C DANSON srl **Formular** nr. **1**

DECLARAŢIE PRIVIND RESPECTAREA OBLIGATIILOR REFERITOARE LA CONDIŢIILE DE MUNCĂ ŞI DE PROTECŢIA MUNCII

Subsemnatul, reprezentant împuternicit al S C DANSON srl, din Bucuresti, sect.2, str.Aurel Vlaicu, nr.39, ap.3, cod020092, declar pe propria răspundere, sub sanctiunile aplicate faptei de fals în acte publice, că la elaborarea ofertei am tinut cont de obligatiile referitoare la conditiile de muncă si protectia muncii si ne angajam sa respectam aceste conditii pe parcursul indeplinirii contractului, in conformitate cu regulile obligatorii referitoare la conditiile de munca si protectia muncii, respectiv din domeniile mediului, social și al relațiilor de muncă, care sunt in vigoare in Romania.

Data completării 30.03.2020

S C DANSON srl,
Director General,
Dan Ionut Stroe,

.....

SOCIETATEA COMERCIALĂ DANSON S.R.L. - BUCURESTI -

aXcent medical GmbH - Josef-Görres-Platz 2 - D-56068 Koblenz

Josef-Görres-Platz 2
56068 Koblenz / Germany
Tel: +49 261 3011 117
Fax: +49 261 3011 111
info@axcentmedical.com
www.axcentmedical.com

LETTER OF AUTHORIZATION

Date:27th August 2018

We **aXcent medical GmbH** , who are the official manufacturers of Anesthesia Machines, ICU Ventilators, Patient monitoring and breathing systems, having factories at **Josef-Görres-Platz 2, 56068 Koblenz – Germany**, do hereby authorize **DANSON SRL, Str. Aurel Vlaicu Nr. 39 Sector 2, Bucuresti – ROMANIA** to distribute and assist in negotiating contracts for goods manufactured and supplied by us.

We hereby extend our full guarantee and warranty as per the warranty clauses of contract conditions for the goods offered for supply by the above firm and duly authorize **DANSON SRL** to fulfill all installation, technical support and maintenance obligations required by the contract.

CONFORM CU ORIGINALUL

Torsten Kullmann
Managing Director

aXcent medical GmbH
Josef-Görres-Platz 2
56068 Koblenz - Germany
Tel.: +49 261 30 11 117 - Fax: +49 261 30 11 111
info@axcentmedical.com - www.axcentmedical.com

aXcent medical GmbH
Josef-Görres-Platz 2
D-56068 Koblenz

Bankverbindung:
Volksbank Koblenz Mittelrhein
SWIFT: GENODE 51KOB
IBAN:DE11 5709 0000 1077 7550 00
Geschäftsführer: Torsten Kullmann
AG Koblenz HR 26221
St.-Nr.: 22/650/07493
UST ID-Nr.: DE318243954

aXcent medical GmbH · Josef-Görres-Platz 2 · D-56068 Koblenz

Josef-Görres-Platz 2
56068 Koblenz / Germany
Tel: +49 261 3011 117
Fax: +49 261 3011 111
info@axcentmedical.com
www.axcentmedical.com

SCRISOARE DE AUTORIZARE

Data: 27 august 2018

Noi aXcent medical GmbH, care sunt producătorii oficiali ai Mașinilor de anestezie, ventilatoarelor UCI, sistemelor de monitorizare și respirație a pacienților, având fabrici la Josef-Görres-Platz 2, 56068 Koblenz - Germania, autorizează prin prezenta DANSON SRL, Str. Aurel Vlaicu Nr. 39 Sector 2, Bucuresti - ROMANIA pentru a distribui și ajuta la negocierea contractelor pentru mărfurile fabricate și furnizate de noi.

Prin aceasta, extindem garanția completă și garanția conform clauzelor de garanție a condițiilor contractuale pentru mărfurile oferite pentru furnizarea de către firma de mai sus și autorizăm în mod corespunzător DANSON SRL să îndeplinească toate obligațiile de instalare, asistență tehnică și întreținere cerute de contract.

Toesten Kullmann
Director General

aXcent medical GmbH
Josef-Gorres-Platz 2
D-56068 Koblenz

CONFORM CU ORIGINALUL

Bankverbindung:
Volksbank Koblenz Mittelrhein
SWIFT: GENODE 51KOB
IBAN:DE11 5709 0000 1077 7550 00
Geschäftsführer: Torsten Kullmann
AG Koblenz HR 26221
St.-Nr.: 22/650/07493
UST ID-Nr.: DE318243954

Subsemnatul Teodorescu Ilie-Tudor, traducător şi interpret autorizat pentru limba engleză, titular al autorizației de traducător nr.10292/08.12.2003, eliberată de Ministerul Justiției, certific exactitatea traducerii din limba Engleză în limba Română cu textul înscrisului în copie, prezentat mie.
The undersigned, Teodorescu Ilie-Tudor, sworn translator and interpreter for English language, holder of the Translator Authorization no.10292/08.12.2013 issued by the Ministry of Justice, I hereby certify the exactness of the translation from English language to Romanian language with the text of the document in copy, presented before me.
Traducător/Translator,
Teodorescu Ilie-Tudor
Autorizație nr./Authorization no.10292/08.12.2013

CONFORM CU ORIGINALUL

SOCIETATEA CAMERALĂ 1 DANSON S.R.L. - BUCUREȘTI -

MINISTERUL SĂNĂTĂȚII
AGENȚIA NATIONALĂ A MEDICAMENTULUI
SI A DISPOZITIVELOR MEDICALE
Str. Av. Sănătescu nr. 48, sector 1, 011478 Bucureşti
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

AVIZ DE FUNCŢIONARE
Nr. 5797 din 09.01.2019

În conformitate cu art. 926 din Legea nr. 95/2006 privind reforma în domeniul sănătăţii, republicată, cu modificarile si completarile ulterioare şi în baza documentaţiei înaintate, Agenția Națională a Medicamentului și a Dispozitivelor Medicale avizează funcţionarea unităţii

DANSON SRL

cu sediul social în Bucuresti, B-dul Dacia nr.81, parte, ap.1, sector 2 şi punct de lucru în Bucuresti, Str.Aurel Vlaicu nr.39, ap.3, sector 2
pentru activităţi de:

import dispozitive medicale | DA | ~~NU~~ | ;

distribuţie dispozitive medicale | DA | ~~NU~~ | ;

depozitare dispozitive medicale | DA | ~~NU~~ | ;

protezare | ~~DA~~ | NU | : ☐ **ortopedică;** ☐ **auditivă;** ☐ **alte tipuri;**

optică medicală | ~~DA~~ | NU | ;

reparare, mentenanţă şi punere în funcţiune/instalare | DA | ~~NU~~ |

pentru dispozitive medicale din urmatoarele domenii :

-ATI (pulsoximetre, monitoare de functii vitale)
-electromecanice (unituri ORL, ecografe, holtere, colposcoape, dispozitive pentru electroterapie, magnetoterapie, unde scurte, microunde, biciclete ergometrice, covoare rulante, EKG-uri, osteodensitometre, spirometre, impedantmetre, timpanometre, endoscoape, mese de examinare generale – ginecologie)
-reutilizabile pentru chirurgie (mese de operatie, aspiratoare chirurgicale)
-oftalmologie si optica medicala (microscoape de examinare)

Unitatea este distribuitor al producătorilor:

Nume producator	Tara	N	SH	CR
ALLTION (WUZHOU) CO.LTD	CHINA	Da		
ALSA APPARECCHI MEDICALI SRL	ITALIA	Da		
AR-EL TIBBI URUNLER SAN.VE TIC. LTD.STI.	TURCIA	Da		
AXCENT MEDICAL GMBH	GERMANIA	Da		
CARDIOLINE SPA	ITALIA	Da		
ELETTRONICA PAGANI SRL	ITALIA	Da		
EMA-LED GMBH	GERMANIA	Da		
GAMIDA TECH	FRANTA	Da		
HADECO INC	JAPONIA	Da		
HUMARES GMBH	GERMANIA	Da		
IDS LTD	COREEA	Da		
INTERMEDIC ARFRAN SA	SPANIA	Da		
KARL KAPS GMBH & CO KG	GERMANIA	Da		
KROBER MEDIZINTECHNIK GMBH	GERMANIA	Da		
MAICO DIAGNOSTIC GMBH	GERMANIA	Da		
MEDICA SPA	ITALIA	Da		
MEDICAL ECONET GMBH	GERMANIA	Da		
MEDLIGHT GMBH	GERMANIA	Da		
MEDSTAR CO LTD	COREEA	Da		
METSIS MEDIKAL TEKNIK SISTEMLER ELEKTRONIK OTO.INS.TUR.VE SAN.TIC.LTD.STI	TURCIA	Da		
MICROMED MEDIZINTECHNIK GMBH	GERMANIA	Da		
SAMSUNG MEDISON CO.LTD	COREEA	Da		
THORNHILL RESEARCH INC	CANADA	Da		
US OPHTHALMIC	SUA	Da		

Unitatea este reprezentant autorizat în Uniunea Europeană al producătorului:

Nu este cazul.

Orice modificare a condiţiilor stabilite prin reglementările Agenției Naționale a Medicamentului și a Dispozitivelor Medicale, care au stat la baza avizării, atrage anularea prezentului aviz de funcţionare.

Valabilitatea prezentului aviz poate fi verificata prin solicitare scrisa adresata Agenției Naționale a Medicamentului și a Dispozitivelor Medicale.

PREȘEDINTE,

ADRIANA COTEL

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 101259 0002 Rev. 01

Manufacturer: **aXcent medical GmbH**
Josef-Görres-Platz 2
56068 Koblenz
GERMANY

Facility(ies): aXcent medical GmbH
Dr.-Walter-Lessing-Str. 4, 56112 Lahnstein, GERMANY

Product Category(ies): **patient monitors, anesthesia devices, ventilators**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713154534

Valid from: 2019-09-13
Valid until: 2023-12-09

Date, 2019-09-13

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 101259 0001 Rev. 01

Holder of Certificate: **aXcent medical GmbH**
Josef-Görres-Platz 2
56068 Koblenz
GERMANY

Facility(ies): aXcent medical GmbH
Dr.-Walter-Lessing-Str. 4, 56112 Lahnstein, GERMANY

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production, distribution and service of patient monitors, anesthesia devices and ventilators**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713154534

Valid from: 2019-09-13
Valid until: 2021-12-09

Date, 2019-09-13

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17

S C DANSON srl

OFERTA TEHNICA

Denumire utilaj : Ventilator de transport

Model : MUSCA X2 , Producator : Axcent Medical , Tara : Germania.

SPECIFICATII	CONFORMITATE		
	Da	Nu	Document / pagina
Sa asigure suport vital pentru pacienti cu insuficienta respiratorie acuta pe durata transportului	X		Conf. Manual pag.15
Circuite cu o singura scurgere, cu o singura supapa si circuite cu doua membre precum si interfete multiple pentru pacienti	X		Conf. Manual pag.31, 41, 42
Sa poata fi utilizat pentru o gama larga de tipuri de pacienti aduti si copii, pacienti cu insuficienta respiratorie acuta protezata mecanic	X		Conf. Manual pag.15
Oxigen suplimentar pentru pacientii care necesita terapie cu oxigen	X		Conf. Manual pag.15
Sa permita debitari de pana la 30L/min, pentru un FiO2 livrat de pana la 95%	X		Conf. Prospect pag.15
Sa poata fi programate pragurile de minim si maxim in inspiratie	X		Conf. Manual pag.53
Asigura suport vital pentru pacientii cu o greutate >5kg	X		Conf. Manual pag.44
Circuite : 1circuit de scurgere, 1circuit cu supapa, 1circuit dublu	X		Conf. Manual pag.
Moduri de terapie : CPAP, (A)CV, P(A)CV, P-SIMV, V-SIMV, PS, P(A)C	X		Conf. Prospect pag.15
Respiratie manuala	X		Conf. Manual pag.18, 35
Ventilatie apnee : volum si presiune	X		Conf. Manual pag.62
Volum Tidal lirat adult : 100-2500ml , copil : 50-300ml	X		Conf. Manual pag.62, 63
Rata respiratorie adult:oprit, 2-50rpm ; pediatrie : oprit, 5-80rpm	X		Conf. Manual pag.62, 63
Date monitorizate :FiO2, afisare in timp real pe ecran Presiune si flux (25Hz) si trend pentru 10 zile	X		Conf. Manual pag.62, 63
Alarme FiO2 si SpO2 atunci cand sunt conectate	X		Conf. Manual pag.22, 23, aparatul nu are modul de SpO2, are posibilitatea de a masura EtCO2 (capnografie) cu cost suplimentar 8.590lei fara TVA
Greutate aparat <5kg	X		Conf. Prospect pag.15, 3,4kg fara sistemul de transport si butelie de oxigen
Baterie interna Litiu -Ion	X		Conf. Prospect pag.15
Timp de utilizare continua >6ore	X		Conf. Prospect pag.15
Nivel acustic : 43dBA ±3dBA	X		Conf. Manual pag.69
Garantie 36 de luni	X		Se asigura garantie de **36 de luni** de la data punerii in functiune

Ofertant:
DANSON srl
Director General
Dan Stroe,
.....

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axcent medical

LYRA x2 Ventilator

User Manual

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Product and company names mentioned herein may be the trademarks of their respective owners.

Contents

1 Safety Information 1

1.1 Definitions 1

1.2 Warning 1

1.3 Caution 5

1.4 Note 6

2 Symbols 7

3 General Information 10

3.1 Intended Use 10

3.2 Noninvasive Ventilation Contraindications 10

3.3 Potential Side Effects during Noninvasive Ventilation 10

3.4 Functional Description 11

3.5 Physical Description 13

4 Preparing for Ventilation 19

4.1 Installing the Patient Tubing Support Arm 19

4.2 Installing the Patient Breathing Circuit 20

4.3 Installing the Humidifier 22

4.4 Installing the Nebulizer 23

4.5 Connecting the Oxygen Supply 24

4.6 Connecting to Primary Power Source 25

4.7 About the Batteries 26

4.8 Starting up the Ventilator 26

4.9 Running the System Check 27

4.10 Ventilator Configuration Overview 28

4.11 Navigating the Graphical User Interface 29

4.12 Shutting down the Ventilator 29

5 Ventilator Settings 31

5.1. Ventilation Mode 31

5.2 Control Settings 32

5.3 Alarm Limits 32

5.4 Standby 34

5.5 System Settings 35

5.6 Other Functions 38

6 Patient Monitoring 39

6.1 Numeric Window 40

6.2 Waveform Window 40

6.3 Loops Window 41

6.4 Trend 41

6.5 Freeze 42

7 Alarms 43

7.1 Responding to Alarms 44

7.2 Alarm List 45

7.3 Silencing Alarms 46

7.4 Event Log 46

7.5 Alarm Troubleshooting Table 47

7.6 Alarm Test 51

8 Special functions 54

8.1 O2 Enrichment 54

8.2 Suctioning Tool 54

8.3 Manual Breath 55

8.4 Inspiratory Hold 55

8.5 Expiratory Hold 55

8.6 Nebulizer 55

8.7 STRC 56

8.8 P0.1 57

8.9 NIF 57

8.10 PEEPi 58

8.11 O2 Therapy 58

8.12 Apnea Ventilation 58

8.13 NIV 59

9 Maintenance 60

9.1 Cleaning, Disinfection and Sterilization 60

9.2 Preventive Maintenance 62

9.3 Disposal 63

9.4 Storage 64

9.5 Repacking and Shipping 64

9.6 Battery Maintenance 64

10 Specifications 68

10.1 Physical Characteristic 68

10.2 Environmental Requirements 68

10.3 Electrical Specifications 69

10.4 Pneumatic Specifications 70

10.5 Control Settings 71

10.6 Monitored Parameters 79

10.7 Alarms 84

10.8 Configuration Specifications 86

10.9 Factory Default Settings 88

A Ventilation Modes 100

B Pneumatic Diagram 107

C Parts and Accessories 108

D Communications Interface 111

E EMC Declarations 112

1 Safety Information

Before using the LYRA x2 ventilator on a patient, familiarize yourself with this user manual, particularly the safety considerations listed. Be aware, however, that this manual is a reference only. It is not intended to supersede your institution's protocol regarding the safe use of assisted ventilation devices.

Warnings and cautions that apply to the use of the ventilator under all circumstances are included in this section. Additional warnings and cautions are also inserted within the manual where they are most meaningful.

Notes are also located throughout the manual to provide additional information related to specific features.

1.1 Definitions

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury or equipment damage.

NOTE

Emphasizes information of particular importance.

1.2 Warning

- The ventilator must only be operated and used by authorized medical personnel well trained in the use of this product. It must be operated strictly following the user manual.
- An alternative means of ventilation shall be available whenever the ventilator is in use. If a fault is detected in the ventilator, disconnect the patient from it and immediately start ventilation with such a device. For example, using a manual respirator.
- Before use, the ventilator, cables and accessories must be inspected to ensure that they can work normally and safely.

- Be aware that a ventilator shutdown for any reason increases the patient's risk of CO2 rebreathing.
- Do not open the equipment housings. All servicing and future upgrades must be carried out by qualified service personnel only.
- Modification of the ventilator and associated equipment is not permitted and may compromise ventilator operation and patient safety. Servicing should only be done by qualified service personnel.
- To ensure the correct performance of the ventilator and the accuracy of patient data, use only aXcent accessories with the ventilator.
- To reduce the risk of electric shock from liquid entering the device, do not put a container filled with a liquid on the ventilator.
- To reduce the risk of fire, use the ventilator in well-ventilated areas away from flammable anesthetics. Do not use in a hyperbaric chamber or other similarly oxygen-enriched environments. Do not use near an open flame.
- Do not use the ventilator with helium or mixtures with helium.
- To reduce the risk of strangulation from patient tubing, use a tubing support arm and secure the proximal pressure line with clips to position the sensor cables and tubing appropriately.
- Manufacturer default settings are not appropriate for all patients. Prior to using the ventilator, verify that the current alarm settings or defaults are appropriate for each particular patient.
- Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level may result in a hazard to the patient. Remember that alarm settings should be customized according to different patient situations and always keeping the patient under close surveillance is the most reliable way for safe patient monitoring.
- The physiological parameters and alarm messages displayed on the screen of the ventilator are for doctor's reference only and cannot be directly used as the basis for clinical treatment.
- To reduce the risk of fire, use only patient circuits intended for use in oxygen-enriched environments. Do not use antistatic or electrically conductive tubing.
- Be sure to set the high inspiratory pressure alarm appropriately to minimize patient risk from overpressurization or early breath termination.

- To minimize patient risk from aspiration of condensate, use either a circuit with water traps or a heated wire circuit.
- The patient's exhaled volume can differ from the measured exhaled volume due to leaks around the mask during noninvasive ventilation. We recommend that you set the leak alarm to detect and notify when a clinically significant leak occurs.
- To prevent possible asphyxia and to reduce the risk of CO_2 rebreathing, take these precautions with respect to mask and exhalation port use:
  - Use only an oro-nasal mask with an anti-asphyxia valve or a nasal mask for noninvasive ventilation.
  - Do not occlude the exhalation port.
- To prevent unintentional disconnection of the power cord, always use the correct aXcent - supplied power cord and lock it into place with the power cord retainer before use.
- To reduce the risk of electric shock, connect the ventilator to an AC supply mains with protective earth only.
- To reduce the risk of electric shock, regularly inspect the AC power cord and verify that it is not frayed or cracked.
- A ventilator shutdown due to a total loss of power during ventilation poses serious risks to the patient. Always have a backup battery installed and fully charged.
- The backup battery must be installed in the ventilator. Periodically check and replace the battery as needed. Refer servicing to qualified service personnel.
- The battery is intended for backup or transport use only. Battery operation time can be affected by discharge and recharge cycles, time, and ambient temperature. Using the battery as primary power source increases patient risk resulting from a ventilator shutdown due to total power loss.
- Use external power source before the batteries are depleted.
- The buzzer of the ventilator alarm 120s and the exhalation valve is open, if the AC power supply and battery are not in place.
- It is the responsibility of the end user to validate the compatibility and use of information transmitted from the ventilator to the device to be connected to the ventilator.
- Do not use this equipment in an MRI environment.
- Dispose of the package material, observing the applicable waste control regulations and keeping it out of children's reach.

- To prevent possible patient injury, Maintenance mode can only be used when the ventilator is disconnected from the patient.
- Nebulization or humidification can increase the resistance of breathing system filters and that you need to monitor the breathing system filters frequently for increased resistance and blockage.
- The ventilation accuracy can be affected by the gas added by use of a nebulizer.
- As required by the relevant rules and regulations, oxygen concentration should be monitored when the equipment is used on the patient. If your ventilator is not configured with such monitoring function or this function is turned off, use a monitor which complies with the requirements of ISO 80601-2-55 for oxygen concentration monitoring.
- As required by the relevant rules and regulations, expiratory carbon dioxide concentration should be monitored when the equipment is used on the patient. If your ventilator is not configured with such monitoring function or this function is turned off, use a monitor which complies with the requirements of ISO 80601-2-55 for expiratory carbon dioxide concentration monitoring.
- Do not move the ventilator before removing the support arm from it, in order to avoid the ventilator getting tilted during the movement.
- To prevent possible device damage, avoid tipping over the ventilator when crossing thresholds.
- To prevent possible device damage, step down the brake when parking the ventilator.
- A turbofan can cause gas to be heated. To reduce the temperature of gas inside the tube and prevent patient injury accordingly, make sure that the length of patient tube from the humidifier to Y piece is greater than 1.2m.
- To reduce the risk that the patient will aspirate condensed water from the breathing circuit, position any humidifier lower than both the ventilator and the patient.

1.3 Caution

- The ventilator is intended for use by healthcare professionals only.
- At the end of the ventilator service life, the equipment and its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products.
- Grounding reliability can only be achieved when equipment is connected to an appropriate voltage receptacle marked “hospital only” or “hospital grade.”
- To prevent possible damage to the ventilator, use only those cleaning agents listed in this manual.
- To prevent possible damage to the ventilator, do not drip or spray any liquids directly onto any surface.
- Do not attempt to sterilize or autoclave the ventilator.
- To reduce the risk of electrical shock, disconnect electrical power from the ventilator before cleaning.
- To reduce the risk of fire, do not use a high-pressure oxygen hose that is worn or contaminated with combustible materials like grease or oil.
- To prevent possible damage to the ventilator, always ship it with the original packing material. If the original material is not available, please contact aXcent to order replacements.
- To prevent possible damage to the ventilator, always secure it to its stand or securely place it on a flat, stable surface that is free of dirt and debris. Do not use the ventilator adjacent to, or stack it with, other equipment.
- Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason make sure that all external devices operated in the vicinity of the equipment comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.
- Before moving the ventilator, make sure its casters and brakes are in good condition.

1.4 Note

- If an alarm persists for no apparent reason, discontinue ventilator use and contact aXcent.
- If you detect any unexplained changes in the performance or visual displays of the ventilator, discontinue ventilator use and contact aXcent.
- Keep this manual close to the ventilator so that it can be obtained conveniently when needed.
- The software of ventilator was developed in compliance with IEC 62304. The possibility of hazards arising from software errors is minimized.
- This user manual describes all features and options. Your ventilator may not have all of them.
- The ventilator is not made with natural rubber latex.
- The user can set high pressure alarm limit in the inspiratory phase. If the pressure reaches the high pressure alarm limit, the “High Pressure” high-level alarm is triggered. The ventilator opens the expiration valve and switches to expiratory phase until the airway pressure reaches the preset PEEP value. If the airway pressure exceeds 85cmH2O, the ventilator opens the safety valve to release pressure. Make sure to set high pressure alarm limit properly to ensure patient safety.

2 Symbols

The following symbols may appear on device labels or packing.

Symbol	Definition
	Manufacturer.
	Date of Manufacture.
SN	Serial number.
	DC Power.
	Temperature limitations at transport and storage.
	Humidity limitations at transport and storage.
	Atmospheric pressure at transport and storage.
	Follow instruction for use. This label on the device points the user to the operator's manual for complete information. In the operator's manual, this symbol cross-references the label.
	Dispose according to Council Directive 2012/19/EU or WEEE (Waste Electrical and Electronic Equipment).
IP21	Indicates the degree of protection provided by enclosure according to IEC 60601-1.
	Type BF Applied part (classification of medical electrical equipment, type B, as specified by IEC 60601-1).
MR	The device is not suitable for use in MRI environment.
	This way up at transport and storage.

Symbol	Definition
	Fragile, handle with care.
	Keep dry at transport and storage.
	Stacking limitations.
	Recyclable materials.
	Attention, consult accompanying section in the operator's manual.
	Equipotentiality
	Fuse
	Power switch
	Battery
$O_2\%$	Oxygen sensor connector
	Oxygen supply connector
RS232	RS-232 connector
HDMI	HDMI connector.
	USB connector
	Inspiration connector
	Expiration connector

Symbol	Definition
	Lock
	Unlock
	Nebulizer connector
	Proximal pressure port
	Alarm Audio pause

3 General Information

3.1 Intended Use

The LYRA x2 ventilator is a mechanical ventilator designed to provide invasive and non-invasive, continuous or intermittent, respiratory support for pediatric and adult patients.

Intended areas of use:

- In the intensive care ward or in the recovery room.
- During transfer of ventilated patients within the hospital.

The LYRA x2 ventilator is intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

3.2 Noninvasive Ventilation Contraindications

- Inability to trigger breath
- Facial or brain injury
- Recent upper airway or esophageal surgery
- Hemodynamic instability
- Gastric distension
- Inability to protect airway

3.3 Potential Side Effects during Noninvasive Ventilation

Advise the patient to immediately report any unusual chest discomfort, shortness of breath, or severe headache. Other potential side effects of noninvasive positive pressure ventilation include: ear discomfort, conjunctivitis, skin abrasions due to mask/patient interface, and gastric distention (aerophagia). If skin irritation or breakdown develops from the use of the mask, refer to the accompanying mask instructions for appropriate action.

3.4 Functional Description

The LYRA x2 ventilator has provide continuous or intermittent ventilator support for pediatric and adult patients. It functions as a pressure/volume support ventilator by providing pressure- or volume-targeted breaths delivered via endotracheal or tracheostomy tube, as well as approved nasal, oro-nasal, and full face masks.

Ventilation types and modes

The LYRA x2 ventilator offers two ventilation configurations: single-limb noninvasive (NIV) and dual-limb invasive (INV). Each offers a range of modes.

For single-limb noninvasive:

- CPAP (Continuous Positive Airway Pressure).
- PCV (Pressure Control Ventilation).
- PPS (Proportional Pressure Support).
- S/T (Spontaneous/Timed).
- VS (Volume Support).

For dual-limb invasive:

- VCV (Volume Control Ventilation).
- PCV (Pressure Control Ventilation).
- VSIMV (Volume Synchronized Intermittent Mandatory Ventilation).
- PSIMV (Pressure Synchronized Intermittent Mandatory Ventilation).
- PRVC (Pressure Regulated Volume Control).
- V^{+}SIMV (PRVC + SIMV).
- CPAP/PSV (Continuous Positive Airway Pressure/Pressure Support Ventilation).
- BPAP (Bilevel Positive Airway Pressure).
- APRV (Airway Pressure Release Ventilation).

The available ventilation modes depend on the product models. See Chapter10.8 “Configuration Specifications”.

Monitoring

The ventilator offers a variety of monitoring capabilities. It displays monitored parameters as numbers. You can also see this data graphically, as a combination of real-time waveforms, Loops

and Trends.

User interface

The ventilator's ergonomic design, including a color touchscreen, a control knob, and key panel, lets you easily access ventilator settings and monitored parameters.

Oxygen monitoring

An integrated sensor measures oxygen in the delivered gas mixture.

Alarms

The ventilator's operator-adjustable and nonadjustable alarms help ensure the patient's safety.

Power and gas supplies

The ventilator uses as its primary power source AC mains. Two backup batteries power the ventilator for a few hours using nominal settings.

The ventilator uses high-pressure oxygen. An integral blower pressurizes gas for delivery to the patient.

NOTE: Oxygen delivered through the compressed gas hose is used as fresh gas.

Communications interface

The ventilator can output data through the RS-232 serial port upon receiving a command from a host computer or bedside monitoring system. The ventilator is equipped with a remote alarm/nurse call connection to activate alarms remotely.

3.5 Physical Description

Breathing circuits and accessories

The below picture shows the ventilator with its breathing circuit and accessories. Contact your aXcent representative for details on breathing circuits and accessories supplied by aXcent.

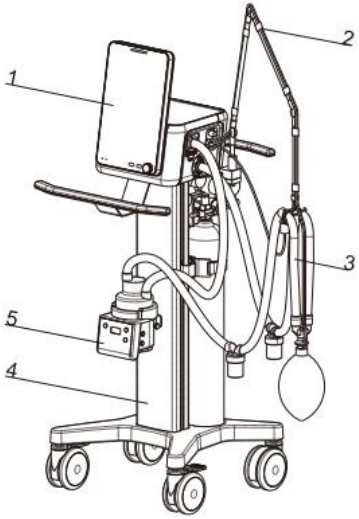


Figure 3-1. Ventilator with Accessories

No.	Description
1	Touch Screen
2	Support arm
3	Breathing circuit
4	Trolley
5	Humidifier

For more information about the compatible breathing circuits and accessories, see Appendix "Parts and Accessories".

Ventilator unit

Figure 3-2 through Figure 3-4 show the controls, indicators, and other important parts of the ventilator unit.

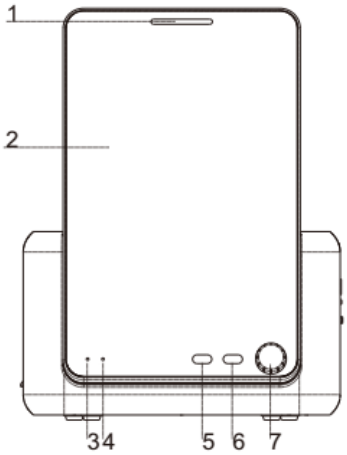


Figure 3-2. Front View

No.	Description
1	Alarm lamp
2	Touchscreen
3	External power supply LED
4	Battery LED Flashes when ventilator is running on battery. On continuously when battery is
5	Alarm Silence key
6	Screen lock/unlock key
7	Control knob

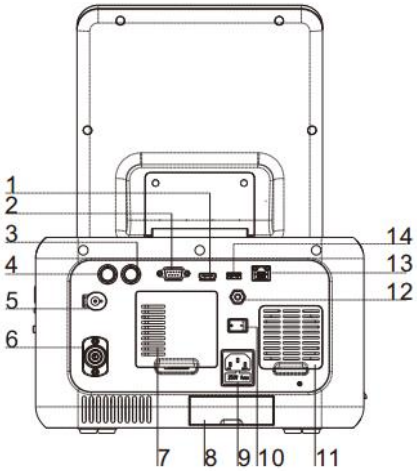


Figure 3-3. Rear View

No.	Description
1	HDMI connector
2	RS-232 connector
3	Reserved for future use
4	Reserved for future use
5	Low-pressure oxygen inlet connector
6	High-pressure oxygen inlet connector
7	High Efficiency Particle Air (HEPA) Filter
8	Removable battery
9	Power cord retainer
10	Power switch
11	Fresh air intake and cooling fan filter
12	Equipotentiality

13	Network connector
14	USB connector

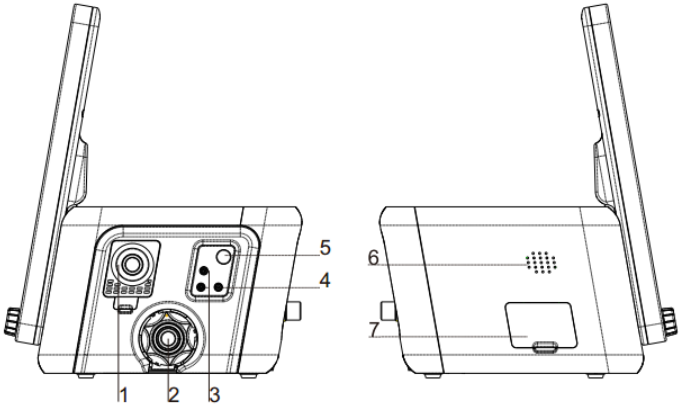


Figure 3-4. Side View

No.	Description
1	Inspiratory filter
2	Expiratory filter. Note: Expiratory filter is not available on RS100.
3	Flow sensor connectors
4	Nebulizer connector
5	Leak test plug
6	Speaker
7	Oxygen Sensor

Screen

Directly access all the windows for mode, controls, alarms, andmonitoring from the screen during normal ventilation. The default screen is shown as below.

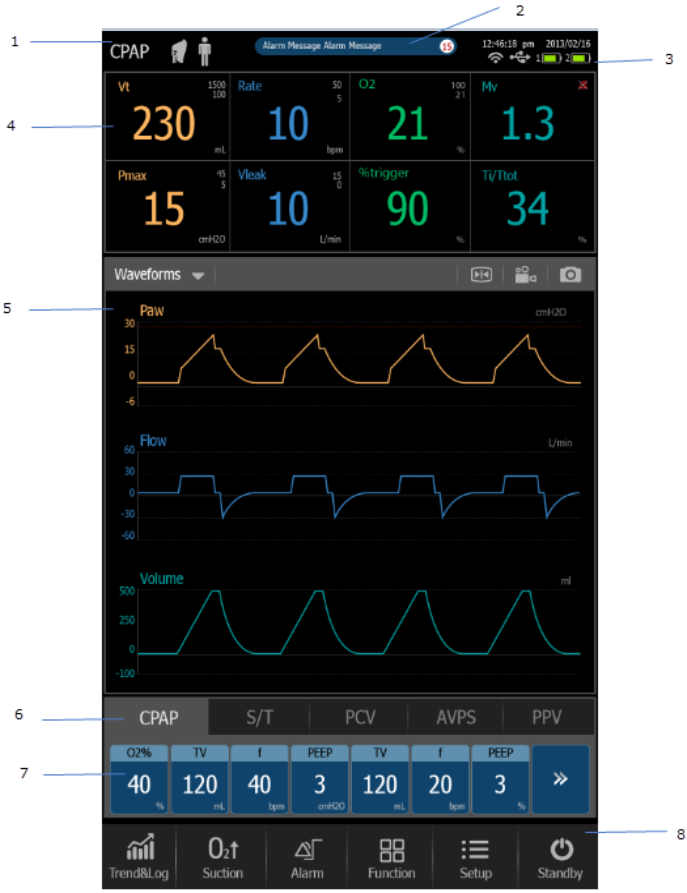


Figure 3-5. Main Screen

No.	Description
1	Active mode, ventilation type and patient group.
2	**Alarm Message bar** Shows the active alarm messages. Touching the Alarm message bar to view the

	alarm messages list.
3	**Indicators bar** Shows the indicators for date, time, batteries level, USB device etc.
4	**Main monitoring parameters** Shows the customized monitoring parameters. The other monitoring parameters can be viewed in the Value window.
5	**Graphic display** Shows the real time waveforms and loops.
6	**Ventilation Modes** Shows all the available ventilation modes. Touching the desired mode label to switch to the corresponding ventilation mode.
7	**Controlling parameters** Shows the main controlling parameters of active mode. Touching the active mode label to view the others controlling parameters.
8	**System Menu** Shows the main feature of ventilator. Touching the menu button to open the feature window.

4 Preparing for Ventilation

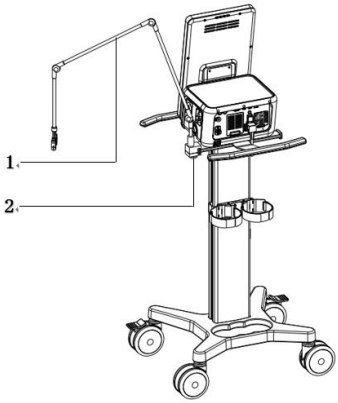
WARNING:

- Do not cover or position the ventilator so as to adversely affect its operation or performance.
- To reduce the risk of the device overheating and possible burn injury, do not block the fan intake at the rear of the ventilator.
- To ensure normal air circulation and exchange, do not cover or block the ports on the ventilator.
- To reduce the risk that an alarm will go unnoticed or be disregarded, do not block the speakers.
- To reduce the risk of electric shock from liquid entering the device, do not put a container filled with a liquid on the ventilator.

Set up the ventilator for each patient use as described in this chapter.

4.1 Installing the Patient Tubing Support Arm

Install the patient tubing support arm on either side of the ventilator trolley. The arm snaps into place.



1. Fixing block. 2. Fixing block knob

Figure 4-1. Installing the patient tubing support arm

1. Loosen the fixing block knob. Place the fixing block onto the handle on the side of the ventilator.
2. Tighten the fixing block knob.

4.2 Installing the Patient Breathing Circuit

Warning:

- To minimize the risk of bacterial contaminationor physical damage, handle bacteria filters withcare.
- To prevent patient or ventilator contamination,always use a bacteria filter between the ventilator and the inspiratory limb of the patient breathing circuit.
- The use of an expiratory filter may lead to a significant increase in expiratory resistance. Excessive expiratory resistance may compromise ventilation and increase patient work of breathing and intrinsic PEEP.
- To reduce the risk of CO2 rebreathing during noninvasive ventilation, avoid introducing extra dead space to the patient circuit.

Install the patient circuit exactly as it will be used on the patient. For a list of compatible parts and accessories offered by aXcent, see Appendix “Parts and Accessories”.

1. Determine the correct patient type. Press the **Adult** button or the **Pediatric** button.
2. Assemble the patient circuit, including the main flow (inspiratory) bacteria filter, proximal pressure line, and HME (if desired).

Figure 4-3 through Figure 4-5 show circuit configurations for single-limb and dual-limb ventilation. Follow the manufacturers’ instructions for use for the individual parts, including the humidifier.

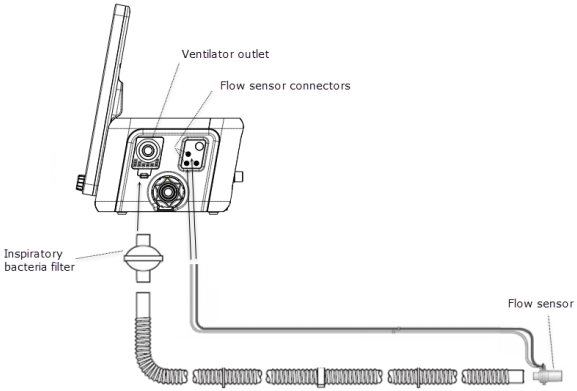


Figure 4-2. Single-limb, noninvasive circuit, without humidification

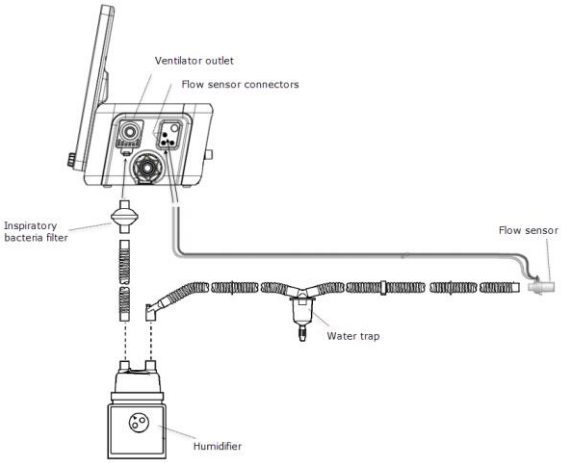


Figure 4-3 Single-limb, invasive circuit, with humidification

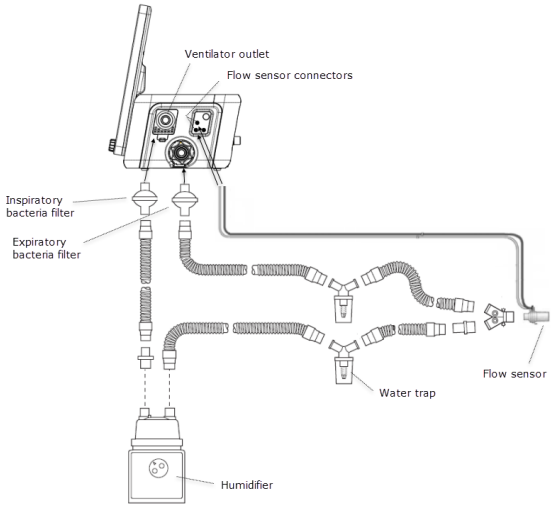


Figure 4-4. Dual-limb circuit with non heated-wire humidification

Properly position the patient circuit before use on a patient. Make sure the tubing will not be pushed, pulled, or kinked during patient movement or other procedures.

4.3 Installing the Humidifier

Warning:

- To prevent possible patient injury and equipment damage, do not turn on the humidifier until the gas flow has started and is regulated.
- To prevent possible patient injury and equipment damage, make sure the humidifier is set to appropriate temperature and humidity.

Note:

- The humidifier shall comply with the requirements of ISO 8185. The humidifier assembly and its installation steps described in this section are only for reference.

Install a humidifier to the ventilator using the slide bracket on the trolley column. Prepare the humidifier as described in the manufacturer's operation manual.

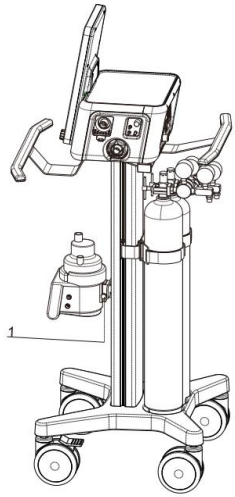


Figure 4-5. Installing the humidifier

4.4 Installing the Nebulizer

Note:

- Install the specified nebulizer. The nebulizer assembly and its installation steps described in this section are only for reference. Refer to the nebulizer user manual for use to install and use the nebulizer.
- To prevent the expiration valve from sticking due to nebulized medications, use only medications approved for nebulization and regularly check and clean or replace the expiration valve membrane.
- Do not use an expiratory filter or HME in the patient's breathing circuit during nebulization. Nebulization can cause an expiratory side filter to clog, substantially increasing flow resistance and impairing ventilation.
- Connect the nebulizer in the inspiratory limb. Connecting the nebulizer between the patient connector and the endotracheal tube increases dead space ventilation.

The nebulization feature provides a stable driving pressure to power a pneumatic nebulizer connected to the nebulizer outlet. Connect the nebulizer and accessories as shown below.

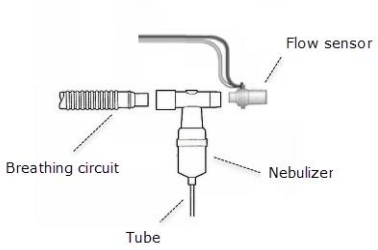


Figure 4-6. Installing a pneumatic nebulizer

4.5 Connecting the Oxygen Supply

WARNING:

- Connect the ventilator only to an appropriate medical-grade oxygen source.
- Inspect the O2 supply connector carefully and make sure there is no leakage. If gas leakage is significant, O2 concentration in the ambient environment will exceed normal atmosphere, resulting in potentially dangerous O2 enriched environment.
- To reduce the risk of hypoxia, connect only oxygen to the high-pressure connector at the rear of the ventilator.

CAUTION:

- To prevent possible damage to the ventilator, ensure that the connection to the oxygen supply is clean and unlubricated, and that there is no water in the oxygen supply gas.
- The ventilator's oxygen control is not active when low-pressure oxygen is used. To prevent possible patient injury, use low-pressure oxygen only in cases where the low-pressure supply can provide an adequate level of oxygenation.
- To prevent possible patient injury, make sure that an emergency backup O2 supply (for example, a gas cylinder) is available in case the low-pressure O2 supply fails.

Oxygen for the ventilator can come from a high- or low- pressure source.
When the high pressure oxygen supply is connected, the normal pressure of the gas source is 280~600KPa. If the gas supply pressure is less than 280KPa, it will compromise the performance of the ventilator and even stop the ventilation.
When the low pressure oxygen supply is connected, the supply of low pressure oxygen does not exceed 15 L / min. To reduce the risk of fire, do not use a low-pressure oxygen supply that delivers a flow rate of more than 15 L / min.

To connect the high-pressure oxygen supply as follows:

1. Before connecting the oxygen supply hose, check if the sealing ring at the gas supply connection is in good condition. If the sealing ring is damaged, do not use the hose and replace the sealing ring to prevent leakage.
2. Align and connect the fitting to the inlet of the high-pressure oxygen supply at the back of the ventilator.
3. Make sure the gas supply hose is connected to the gas supply inlet, then tighten the hose nut.

To connect the low-pressure oxygen supply as follows:

1. Depress the metal dome on the low-pressure oxygen supply connector.
2. Align the oxygen supply hose with and insert it into the low-pressure oxygen supply connector.

4.6 Connecting to Primary Power Source

WARNING:

- To reduce the risk of electric shock, connect the ventilator to an AC supply mains with protective earth only.
- To reduce the risk of electric shock use only a aXcent-supplied (hospital-grade) power cord and connect the ventilator only to supply mains with protective earth.
- To reduce the risk of strangulation, route the power cord to avoid entanglement.

CAUTION:

Grounding reliability can only be achieved when equipment is connected to an appropriate voltage receptacle marked “hospital only” or “hospital grade.”

Connect the ventilator to an outlet that supplies AC power between 100 and 240 V AC, 50/60 Hz. Always checkthe reliability of the AC outlet. If you are using a 120 V outlet, make sure that it is hospital-grade.

4.7 About the Batteries

Warning:

To reduce the risk of power failure, pay close attention to the battery's charge level. The battery's operation time is approximate and is affected by ventilator settings, discharge and recharge cycles, battery age, and ambient temperature. Battery charge is reduced at low ambient temperatures or in situations where the alarm is continuously sounding.

Note:

The backup batteries are intended for short-term use only. They are not intended to be a primary power source.

The ventilator comes with two backup batteries, one mandatory and the other optional, The backup batteries protects the ventilator from AC power interruptions. If AC power fails, the ventilator automatically switches to operation on backup batteries with no interruption in ventilation. The batteries powers the ventilator until AC power is restored or until the battery is depleted. The battery powers the ventilator typically for a few hours.

The ventilator charges the batteries whenever the ventilator is connected to AC, with or without the ventilator switched on. The battery LED flashes to show that the battery is using.

Check the batteries charge level before putting a patient on the ventilator and before unplugging the ventilator for transport or other purposes. If the ventilator is running on batteries, the level of batteries charge is shown at the top right-hand corner of the screen. If the battery is not fully charged, recharge it by connecting the ventilator to AC power.

4.8 Starting up the Ventilator

Switch on the ventilator power switch. The alarm indicator light flashes yellow and red once in turn and then the speaker and the buzzer give a check sound respectively.

After a short time, a start-up screen appear. Then the System Check window is displayed, you

can run the system self-test before using the ventilator.

4.9 Running the System Check

The system check is performed by following the on-screen steps, instructions, and messages. Make sure the tests pass before you return the ventilator to clinical use.

We recommend that you run system check when:

- Before placing a new patient on the ventilator.
- After installing a new or decontaminated breathing circuit or component.
- When the oxygen sensor is replaced.

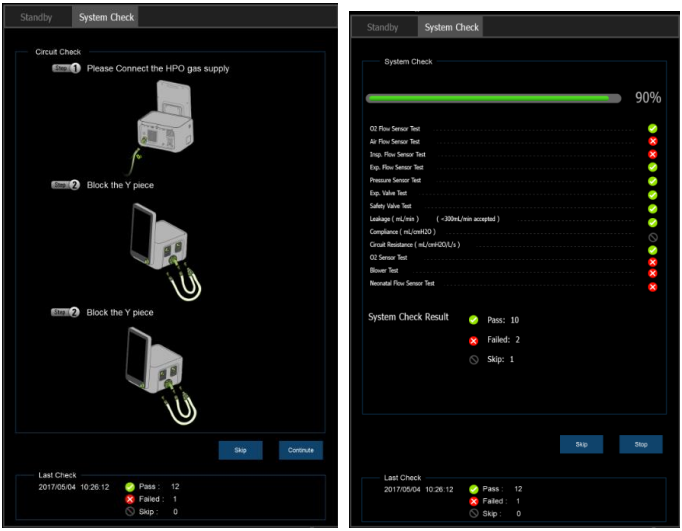


Figure 4-7. System Check

The System Check for INV including the below items:

- Blower Test
- Inhalation Branch Test
- O2 Branch Test
- O2 Cell Test
- Exhalation Branch Test
- Pressure Sensor Test

- Leakage（mL/min）
- Compliance （mL/cmH2O）
- Circuit Resistance （cmH2O/L/s）

The System Check for NIV including the below items:

- Blower Test
- Inhalation Branch Test
- O2 Branch Test
- O2 Cell Test
- Pressure Sensor Test

4.10 Ventilator Configuration Overview

After the Systgem Self-Check pass, the ventilator configuration is displayed on the Standby Windows. You can set up the patient type, patient circuit, and components of the breathing system for new and resuming patients.

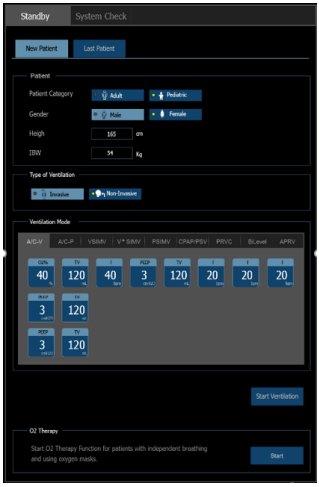


Figure 4-8. Ventilator Configuration

Configuring a New Patient

1. Select **New Patient** from the Standby window.
2. Select settings for patient type, circuit type, and ventilation mode that depending on which type of circuit you chose.
3. Adjust the control settings of the ventilation mode as needed.

Then you can press the **Start Ventilation** button to start ventilation.

Resume a Patient

Select **Las Patient** from the Standby window. The ventilator will start up with the same mode and settings as last power down. Then you can press the **Start Ventilation** button to start ventilation.

4.11 Navigating the Graphical User Interface

Use the touchscreen to access the ventilation menu on the screen. Use the press-and-turn knob to adjusting the ventilation parameters.

To open a window, touch the Menu button on the screen.

To close a window, touch the Menu button or the button in the upper left-hand corner of the window.

To adjust a parameter, touch the parameter button on the screen, the adjustment window will be popup. Using the scroll bar to adjust the control value quickly, or touching the **Plus** or **Minus** button increment or decrement the control value step by step. Touch the **Check** button to apply the changing.

Figure 4-9. Parameter Settings

4.12 Shutting down the Ventilator

NOTE:

The ventilator remains connected to power when the power switch is switched off. This permits the batteries to charge. To completely disconnect the ventilator from power, unplug it

from the mains power outlet.

To shut the ventilator down, please access the standby mode first, then press the power switch for > 3 s on the standby window.

5 Ventilator Settings

5.1. Ventilation Mode

Note:

- The PCV and PSIMV are the recommended ventilation modes for use with a closed-suction catheter. And the settings are decided by the operator according to the patient situation.

The active ventilation mode and control settings are displayed in the bottom of the screen. The displayed modes depends on the ventilation type and product model. For details about modes, see Appendix “Ventilation Modes”.

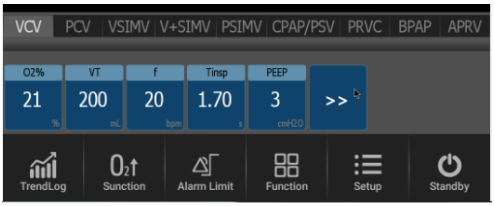


Figure 5-1. Ventilation Modes Menu

To change the mode as follows:

1. Click the desired mode label. A mode window with all the control settings of the selected mode will be popup.
2. Adjust the control settings as needed.
3. Click the **Start** button to confirm the selected mode.

Figure 5-2. Controls of the Selected Modes

5.2 Control Settings

The key control settings of the active ventilation mode are displayed on the bottom of screen. You can adjust them using by touchscreen or knob as needed. Or touch the active mode button to view all the control settings, including the apnea control settings if the apnea backup mode is available in active mode.

For control setting ranges and standard settings, see Table 10.5.

Figure 5-3. Ventilation Mode Control Settings

Figure 5-4. Adjusting the Control Settings

5.3 Alarm Limits

WARNING:

- To prevent possible patient injury, avoid setting alarm limits to extreme values, which can render the alarm system useless.
- To reduce patient risk from inappropriate ventilatory support, avoid turning off the alarms.

The Alarm Limits window displays the operator adjustable alarm settings.

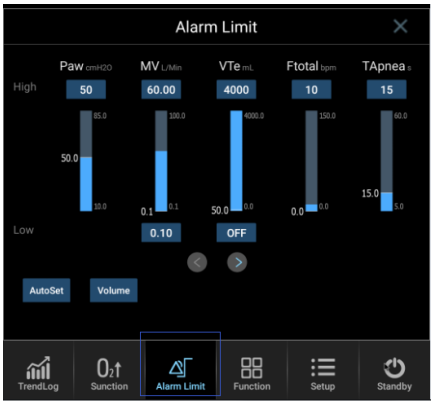


Figure 5-5. Adjusting the Control Settings

Review and adjust the alarm settings as follows:

1. Press the "Alarm Limit" on the screen menu to open the Alarm Settings window.
2. Select a parameter and adjust the value. Repeat for any other desired parameters.
3. Select Accept to apply. The ventilator alarms when a monitored value goes out of the range bounded by the alarm limits.

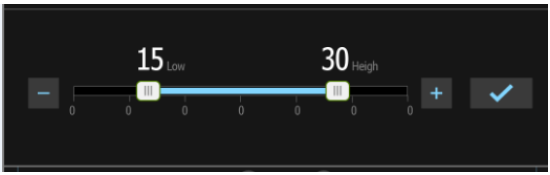


Figure 5-6. Adjusting the Alarm Settings

See chapter 10.7 "Alarms" for the details of alarm settings.

Adjusting Alarm Loudness

Adjust the alarm loudness as follows:

1. Click the **Volume** button on the Alarm Limit window.
2. Adjust the Loudness value as desired.

5.4 Standby

Warning:

- To prevent possible patient injury due to lack of ventilatory support, secure alternative ventilation for the patient before entering the standby mode. Make sure that no patient is attached before entering standby.
- To prevent possible patient injury or damage to breathing circuit from overheated gas, please turn off the humidifier when entering standby.

Standby is a waiting mode that lets you safely suspend ventilation to temporarily disconnect the patient from the ventilator or to set up the ventilator before connecting the patient. Alarms are disabled and oxygen is turned off during standby.

You can also change ventilator settings and most menu functions during standby. The settings changes are effective when you exit standby.

To access the standby mode, click the **Standby** button on the button of the s.creen.

To start ventilation from Standby Mode, Click **Start Ventilation** button.

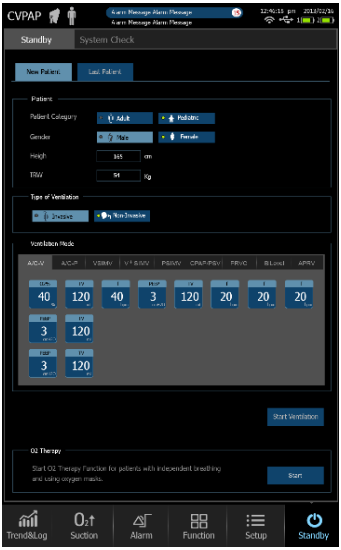


Figure 5-7. Standby Mode

5.5 System Settings

5.5.1 Sensor Settings

The Sensor Settings window lets you run the calibrations for Pressure, Flow and Oxygen sensors.

Figure 5-8. Sensor Settings

5.5.2 Ventilation Settings

The Ventilation Settings window lets you setup the configuration for Ventilation.

Figure 5-9. Ventilation Settings

Item	Description

Tinsp/I:E	Set up whether to set the inspiratory time over the parameter TI or I:E.
VT/IBW	Set up the VT/IBW ratio. The default VT value in ventilation mode will be set based on the selected ratio.
O2 Level	Set up the O2 concentration during O2 Enrichment.
STRC	Set up the Synchronized Tube Resistance Compensation (STRC) configuration. **Tube Type** Select the tube type for Compensation or disable the STRC feature. **Tube Size** Select the tube size of patient circuit. **Compensation** Set up the percentage of compensation. **Expiration** Turn on/off the expiration compensation.

5.5.3 General Settings

The General Settings window lets you setup the configuration for common features, such as system date, system time or screen brightness.

Figure 5-10. General Settings

Item	Description
Language	Set up the system displayed language.
Date	Set up the system date.
Date Format	Set up the system date format.
Time	Set up the system time.
Time Format	Set up the system time format.
Brightness	Set up the screen brightness for day and night. You can enable the automatic dimming feature.
O2 Supply	Set up the O2 supply source.

5.6 Other Functions

Screen Lock

The **Screen Lock** function lets you deactivates all buttons and tabs on the touchscreen. You can press the **Screen Lock** button on the bottom of the monitor to enable the Screen Lock function, and press again to disable it.

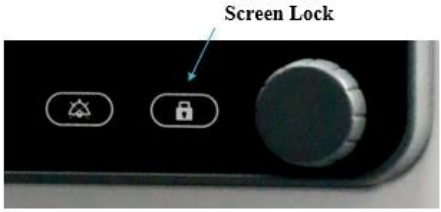


Figure 5-11. Screen Lock Key

6 Patient Monitoring

During ventilation, the ventilator displays the patient data on the screen, you can configure the screen layout with different waveforms, loops, values or trends to suit your institution's needs.

Figure 6-1. Monitoring Window

Press Waveforms button to switch displaying loop windows or values window.

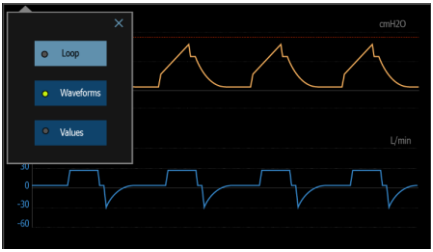


Figure 6-2. Switching Monitoring Window

6.1 Numeric Window

The ventilator displays the numeric patient data on the screen. You can configure the main monitored parameters which are always displayed on the top of the screen. All the monitored parameters can be viewed in the values window.

Figure 6-3. Key Monitored Parameters Window

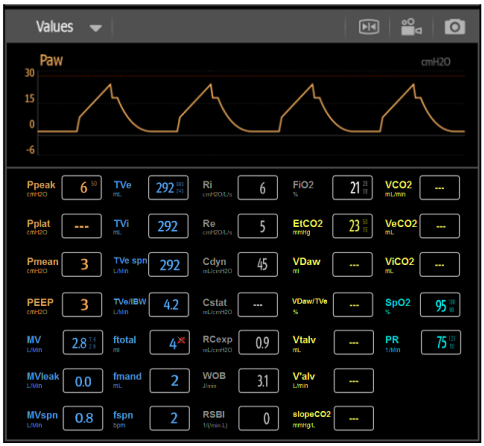


Figure 6-4. Value Window

6.2 Waveform Window

The ventilator displays the real-time pressure/time, flow/time and volume/time waveforms in the waveforms window.

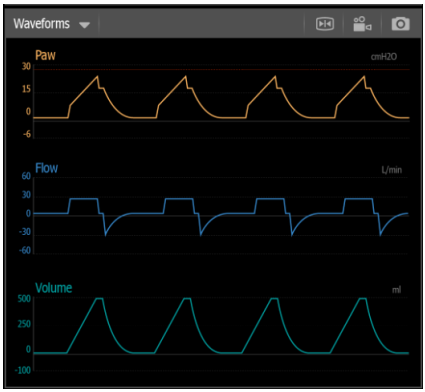


Figure 6-5. Waveforms Window

6.3 Loops Window

The ventilator displays the two real-time loops in the loops window. To view the different type of loop: Pressure-Volume, Pressure-Flow or Flow-Volume, Click the drop-down menu and select the loop type you desired.

Figure 6-6. Loops Window

6.4 Trend

The Trend function lets you view the monitored parameters trends for the past period since you switched on the ventilator. You can choose to show monitored parameters as 1-, 3-, 6-, 12, 24, 48, or 72-hour trends since you switched on the ventilator for the past 1, 3,6, 12, 24,48 or 72 hours.

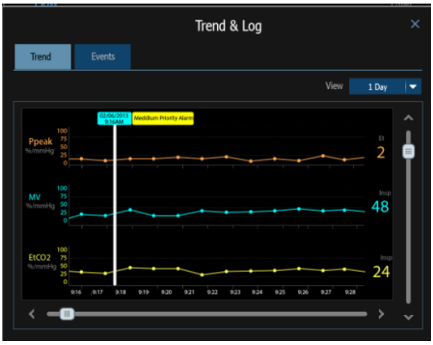


Figure 6-7. Trends Window

6.5 Freeze

This Freeze function lets you freeze the display of the waveforms or loops. it is particularly useful when you perform a breath hold maneuver.

To freeze the graphs, click the **Freeze** button on the top of the graphic window. when the graphs is frozen, a cursor is visible in the middle of the graphs window. You can reposition the cursor by touching the cursor directly. The data values at cursor location for pressure, flow, and volume are displayed in the graphs window.

To unfreeze the graphs, click the Freeze button again.

Figure 6-8. Freeze Waveforms

7 Alarms

The ventilator's alarms notify the operator of problems. These alarm types, including their audiovisual characteristics and required actions, are summarized in Table 7.1. You can view active or inactive alarms, as applicable, in the Alarm list window. Information about the alarm is also stored in an event log.

When a low-, medium-, or high-priority alarm occurs, ventilation typically continues. When the condition that caused the alarm is corrected, the ventilator automatically resets the alarm.

Table 7.1 Alarm indications

Alarm Type	Message Bar	Alarm Lamp	Alarm Audio	Action Require
High-priority	Red, with alarm message	Red	A sequence of 5 beeps, repeated until the alarm is reset.	The patient's safety is compromised. The problem needs immediate attention.
Medium-priority	Yellow, with alarm message	Yellow	A sequence of 3 beeps, repeated periodically.	The patient needs prompt attention.
Low-priority	Blue, with alarm message	Blue	Two sequences of beeps. This is not repeated.	Operator awareness is required.

The Alarm Message Bar is displayed on the top of screen when an alarm is triggered, you can press it to open the Alarm List window for details, or press the history alarm icon to see the inactivating alarms.

Figure 7-1. Alarm Signals on Screen

7.1 Responding to Alarms

Respond to an alarm as follows:

1. Approach the patient immediately. Secure sufficient and effective ventilation for the patient if required. You may silence the alarm if possible.
2. Correct the alarm condition, referring to the alarm messages in Table 7.2.

You can modify alarm settings at any time through the **Alarm Limit** window. When the alarm triggering condition is corrected, the ventilator automatically resets the alarm. For a technical fault alarm, switch off ventilator power first, then correct the problem.

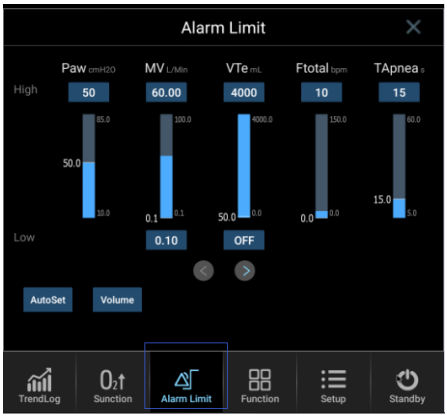


Figure 7-2. Alarm Limit window

7.2 Alarm List

The Alarm button is displayed on the top of screen while the active alarms happen. Click the Alarm button to open the Alarm List window which shows the most recent active alarms. If no alarms are active, the alarm buffer shows the most recent inactive alarms. You can click **Reset** button to clear all the inactive alarms in the Alarm List window.

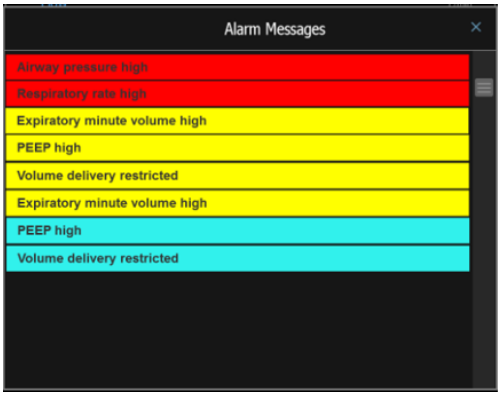


Figure 7-3. Active Alarms Window

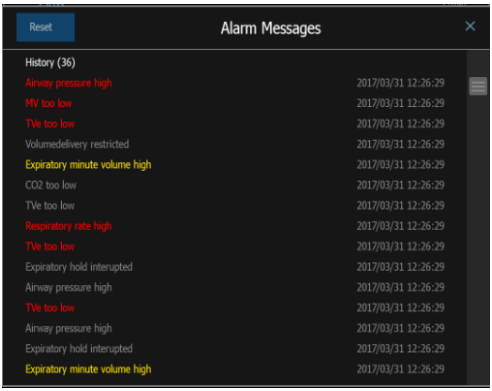


Figure 7-4. History Alarms Window

7.3 Silencing Alarms

NOTE:

- When alarm audio is silenced, all the alarm indicators work normally except audible alarm tones.
- When alarm audio is silenced, if a new alarm occurs, the alarm audio will be restored automatically.

Silence an alarm for 2 minutes by pressing the **Alarm Silence** key on the bottom of the monitor.

When alarm audio is silenced, press the **Alarm Silence** key again to recover the alarm audio.

Figure 7-5. Alarm Silence Key

7.4 Event Log

The Event Log window shows the event log, or data about clinically relevant ventilator occurrences since the ventilator was powered on, including alarms, setting changes, calibrations, maneuvers, and special functions. The date, time, and description are included. If last patient is selected data before the ventilator was turned off is available.

7.5 Alarm Troubleshooting Table

The below table is a list of the alarm messages displayed by the ventilator, along with their definitions and suggested corrective actions. These corrective actions are sequenced to correct the most probable malfunction or to present the most efficient corrective action first. The proposed actions, however, may not always correct the particular problem.

Table 7.2 Alarm Messages

Alarm	Priority	Definition	Action needed
High Pressure	High	The measured inspiratory pressure exceeds the set Pressure alarm limit.	Check the patient. Adjust the Pressure alarm limit. Check the breathing circuit and Flow Sensor tubes for kinks and occlusions. Provide alternative ventilation once the ventilator enters the ambient state.
High Minute Volume	High	The measured Minute Volume is greater the set alarm limit.	Check the patient. Check and adjust the ventilator settings, including alarms.
Low Minute Volume	High	The measured Minute Volume is less the set alarm limit.	Check the patient. Check the breathing circuit. Check and adjust the ventilator settings, including alarms.
High Tidal Volume	Medium	The measured tidal volume is greater than the set high alarm limit.	Reduce the support pressure setting. Adjust the high tidal volume alarm limit.

Alarm	Priority	Definition	Action needed
Low Tidal Volume	Medium	The measured tidal volume is less than the set high alarm limit.	Check the patient. Check and adjust the ventilator settings, including alarm limits. Check for leaks and disconnects.
High Frequency	Medium	The measured frequency is greater than the set alarm limit.	Check the patient for adequate ventilation. Adjust the high frequency alarm limit.
Low Frequency	Medium	The measured frequency is less than the set alarm limit.	Check the patient. Adjust the low frequency alarm limit.
Apnea	High	No patient trigger within the operator-set Apnea time in ventilation mode.	Check the patient.
High Oxygen	High	Measured Oxygen is greater the set alarm limit (low-pressure oxygen) or the operator-set Oxygen + 5% (high-pressure oxygen).	Calibrate the oxygen cell. Install a new oxygen cell.
Low Oxygen	High	Measured Oxygen is less the set alarm limit (low-pressure oxygen) or the operator-set Oxygen - 5% (high-pressure oxygen).	Check the patient. Check the oxygen supply. Provide an alternative source of oxygen, if necessary. Calibrate the oxygen cell. Install a new oxygen cell.

Alarm	Priority	Definition	Action needed
High pressure during sigh	Low	A sigh cannot be fully delivered.	Check the patient. Check the breathing circuit. Adjust the Pressure alarm limit. Consider disabling the sigh function.
High Sustained Airway Pressure	High	The measured airway pressure is greater than or equal to the setting PEEP+15cmH2O for continuous 15s.	Check the patient. Check the ventilation parameter setup. Check the breathing tubes for occlusion.
Patient Disconnected	High	The patient circuit is disconnected from the ventilator.	Check the patient. Reconnect patient circuit. If problem persists, provide alternative ventilation.
Patient circuit leak	Low	The breathing circuit is leaky.	Check the breathing circuit for leakage. Run system self-test to test the leakage.
Patient circuit occluded	High	The breathing circuit is occluded.	Check and clean the breathing circuit. Check and clean the expiration valve.
Flow sensor calibration needed	High	The flow sensor does not have correct calibration data or automatic recalibration of the flow sensor is impossible.	Check the flow sensor. Try to calibrate the flow sensor.
O2 cell defective	Medium	The oxygen cell is depleted.	Install a new oxygen cell.

Alarm	Priority	Definition	Action needed
O2 cell missing	Low	There is no signal from the oxygen cell.	Install an oxygen cell or use an external monitor.
Oxygen Supply Failed	High	O2 pressure is low or high-pressure O2 is not connected.	Check the patient. Check connection with O2 supply. Check O2 supply pressure.
O2 cell calibration needed	Medium	Oxygen cell calibration data is not within expected range, or cell is new and requires calibration.	Calibrate the oxygen cell.
Battery Low	High	The ventilator is running on battery, and the battery capacity is less than 15%.	Connect the ventilator to its external power source.
Battery Temperature high	High	The battery temperature is higher than expected during discharge.	Connect the external power supply. Remove the ventilator from the
Battery missing	High	No battery is present.	Insert a battery.
Running on internal battery	Low	System is powered by the internal battery.	Connect ventilator to AC power when available.
HEPA replacement suggested	Low	The air inlet HEPA filter shows increased resistance.	Replace the HEPA filter.
Realtime clock failure	Low	Date and time not set.	Set date and time and restart the.
Fan failure	Medium	The cooling fan is malfunctioning.	Disconnect the ventilator from the patient. Have the ventilator serviced.

Alarm	Priority	Definition	Action needed
High PEEP	High	The measured positive end expiratory pressure is greater than or equal to	Check the patient. Confirm ventilator and alarm settings are appropriate.
High Blower Temperature	High	The blower temperature is too high.	The ventilation will be stopped. Contact service personnel.
Inspiratory Gas Temperature High	High	The gas temperature exceeds 45℃.	Disconnect the patient. Restart the ventilator.
Speaker Failure	High	The Speaker fails in self-test.	Contact service personnel.
Screen Failure	High	The blank screen occurs.	Contact service personnel.

7.6 Alarm Test

The Ventilator performs a self-check during start-up and continuously during operation. You may want to run alarm tests to demonstrate the alarm's operation.

High Pressure

1. Make sure a demonstration lung is connected to the ventilator and start ventilation in PCV mode normally.
2. Set the Paw high alarm limit to current Peak+5cmH2O.
3. Squeeze the demonstration lung hard during inspiration.
4. Verify that the **High Pressure** alarm is activated, the ventilator cycles into exhalation, and airway pressure falls to PEEP level.

High Tidal Volume

1. Make sure a demonstration lung is connected to the ventilator and start ventilation in VCV mode normally.
2. Set the VT high alarm limit to be less than the current VTe.

3. Verify that the **High Tidal Volume** alarm is activated.

Low Tidal Volume

1. Make sure a demonstration lung is connected to the ventilator and start ventilation in VCV mode normally.
2. Set the VT low alarm limit to be greater than the current VTe.
3. Verify that the **Low Tidal Volume** alarm is activated.

Low Minute Volume

1. Make sure a demonstration lung is connected to the ventilator and start ventilation in VCV mode normally.
2. Set the MV low alarm limit to be greater than the current MV.
3. Verify that the **Low Minute Volume** alarm is activated.

High PEEP

1. Make sure a demonstration lung is connected to the ventilator and start ventilation in PCV mode normally.
2. Nip the inspiration tube with the hands.
3. Verify that the **High PEEP** alarm is activated.

Patient Circuit Occluded

1. Make sure a demonstration lung is connected to the ventilator and start ventilation in PCV mode normally.
2. Nip the inspiration tube with the hands, make sure the monitoring value of VTi is lower than 10 ml.
3. Verify that the **Patient Circuit Occluded** alarm is activated after several breathing cycles.
4. Loosen the inspiration tube and verify this alarm is reset automatically.

High Oxygen

1. Connect the ventilator to low-pressure oxygen supply. Set the oxygen supply type to LPO.
2. Make sure a demonstration lung is connected to the ventilator and start ventilation normally.
3. Set the oxygen high alarm limit to be less than the current oxygen concentration monitored value after ventilation is stable.
4. Verify that the **High Oxygen** alarm is activated.

Low Oxygen

1. Connect the ventilator to high-pressure oxygen supply. Set the oxygen supply type to HPO.
2. Make sure a demonstration lung is connected to the ventilator and start ventilation normally.
3. Switch off the high-pressure oxygen supply after ventilation is stable.
4. Verify that the **Low Oxygen** alarm is activated.

Running on Internal Battery

1. Connect the ventilator to AC power and push the power switch.
2. Disconnect the AC power after the system starts up.
3. Verify that the **Running on Internal Battery** alarm is activated and the ventilator is powered by batteries.
4. Reconnect the AC power.
5. Verify that the alarm resets and the ventilator is powered by AC again.

Battery Low

1. Connect the ventilator to AC power and push the power switch.
2. After the system starts up, disconnect the external power supply when the battery is fully charged.
3. Make sure a demonstration lung is connected to the ventilator and start ventilation normally.
4. The ventilation time is approximately 4 hours for the ventilator configured with one battery (approximately 8 hours for the ventilator configured with two batteries). The battery capacity is to be depleted. The **Battery Low** alarm is activated.
5. Reconnect the external power supply.
6. Verify that the alarm resets and the ventilator is again powered by external power supply.

8 Special functions

8.1 O2 Enrichment

NOTE:

Oxygen alarms are suppressed while the O2 enrichment function is active.

O2 enrichment is not available with low pressure oxygen mode.

When the patient type is adult, the O2 enrichment function delivers 100% oxygen for 2 minutes. When the patient type is pediatric, the applied oxygen concentration during the enrichment maneuver is increased by 25% of the last oxygen setting (e.g. last oxygen setting 60%, resulting oxygen concentration during O2 enrichment maneuver 75%). This is useful for pre- or post-oxygenation before/after tracheal suctioning or for other clinical applications.

To start oxygen enrichment, press the O2 Suction button directly. After a short time, which is required for the oxygen concentration to rise, the ventilator starts delivering 100% oxygen (adult) or the current oxygen setting increased by 25% of the setting (pediatric). Afterwards the ventilator resets the concentration to the previous operator-set value.

To terminate delivery of O2 enrichment before the 2-min period is up, press the key again.

Figure 8-1. O2 Enrichment

8.2 Suctioning Tool

During suctioning, the patient's secretion can escape of the tubing. By using the suctioning tool the ventilation stops and prevents that secretion escapes.

1. To perform the suctioning manoeuvre press the O2 Enrichment button for pre-oxygenation.
2. Disconnection terminates the ventilation and starts the manoeuvre. For 60 seconds, all alarms are completely suppressed.

3. After reconnection the post-oxygenation starts and also for 60 seconds all acoustic alarms are suppressed. The alarm message and lamp is still active.
4. To terminate the pre- and post oxygenation manoeuvre press the O2 enrichment key.

8.3 Manual Breath

The Manual Breath function lets you deliver a manually triggered breath. Press and release the Manual Breath button on the Function window during exhalation.

If you try to initiate a manual breath during the early stage of inspiration or the early stage of exhalation, the breath will not be delivered.

8.4 Inspiratory Hold

The **Inspiratory Hold** function lets you perform an inspiratory hold maneuver.

To perform an inspiratory hold as follow:

1. Open the **Function** -> **Maneuvers** window.
2. Hold the button down during the stage of inspiration, it performs a hold maneuver at the end of inspiration, lasting until the key is released, for up to 30 s additional.

8.5 Expiratory Hold

The **Expiratory Hold** function lets you perform an expiratory hold maneuver.

To perform an expiratory hold as follows:

1. Open the **Function** -> **Maneuvers** window.
2. Hold the button down during the stage of exhalation, it performs a hold maneuver at the end of exhalation, lasting until the key is released, for up to 30 s additional.

8.6 Nebulizer

The nebulization function powers a standard inline nebulizer for delivery of prescribed medications in the ventilator circuit. When nebulization is active, the nebulizer flow is synchronized with the inspiratory phase of each breath for 30 min. Nebulization can be activated in all modes of ventilation.

To start nebulization as follows:

1. Open the **Function** -> **Maneuvers** -> **Nebulization** window.
2. Set up the time period for nebulization.
3. Press the **Start** button to begin nebulization. To terminate nebulization press the button again.

8.7 STRC

Waring:

- Using the incorrect tube type or size setting can endanger the patient. To prevent possible patient injury due to inappropriate compensation, make sure to set these appropriately.
- STRC may induce auto triggering. If auto triggering occurs, first check the patient, breathing circuit, and other settings as possible causes before lowering the Compensate setting or disabling STRC.

To reduce the patient's work of breathing while on the ventilator, the ventilator's synchronized tube resistance compensation (STRC) feature offsets the flow resistance imposed by the endotracheal (ET) or tracheostomy (Trach) tube. STRC is active during inhalation. The compensation during exhalation can be optionally set.

To enable or disable STRC and adjust the settings as follows:

1. Open the **Menu** -> **Ventilation** window.
2. Select **ET tube** (endotracheal tube), **Trach tube** (tracheostomy tube), or **Disable STRC**.
3. If you selected **ET tube** or **Trach tube**, adjust the **Tube ID** and **Compensate** settings. If the ET tube is shortened, lower the **Compensate** setting.
4. Select **Expiration** to activate compensation during exhalation.
5. Confirm by selecting **Apply**.

8.8 P0.1

The airway occlusion pressure (P0.1) maneuver is used to determine the patient's neuromuscular drive to breathe. The P0.1 results are based on a four-breath average. This maneuver cannot be attempted while any alarm is active.

To perform the P0.1 as follows:

1. Open the **Function** -> **Diagnostics** window.
2. Select **P0.1** on the screen.
3. Click **Start** button to start the measurement, and the result will be displayed after the measurement is completed.

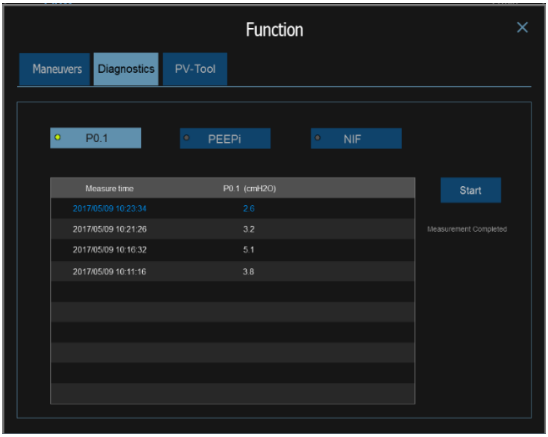


Figure 8-2. Diagnostics of Special Functions

8.9 NIF

The Negative Inspiratory Force (NIF) maneuver is used to determine the patient's ability to pull a negative inspiratory pressure against an occluded airway.

To perform the NIF as follows:

1. Open the **Function** -> **Diagnostics** window.
2. Select **NIF** on the screen.
3. Click **Start** button to start the measurement, and the result will be displayed after the measurement is completed.

8.10 PEEPi

The Intrinsic PEEP (PEEPi) maneuver is used to measure the PEEPi and Vtrap. PEEPi is the positive end-expiratory pressure produced by the trapped gas and Vtrap is the trapped gas volume.

To perform the PEEPi as follows:

1. Open the **Function** -> **Diagnostics** window.
2. Select **PEEPi** on the screen.
3. Click **Start** button to start the measurement, and the result will be displayed after the measurement is completed.

8.11 O2 Therapy

O2 therapy is a method to increase O2 concentration in the airway at normal pressure through simple tube connections. O2 therapy is a way for hypoxia prevention or treatment, providing O2 concentration higher than that in the air.

To start O2 Therapy, Click the **Standby** button to enter the Standby mode, the Click the Start button for O2 Therapy.

8.12 Apnea Ventilation

The LYRA x2 ventilator provides apnea backup ventilation, a mechanism that minimizes possible patient injury due to apnea or cessation of respiration. Apnea can occur in any spontaneous mode, that is, one that relies solely on the patient to trigger. When the ventilator detects no inspiratory efforts or delivers no control breaths during the operator-set Apnea interval, it annunciates an Apnea alarm and starts apnea backup ventilation. It provides ventilation at the operator-selected apnea settings.

If the patient triggers two consecutive breaths, or the alarm is reset, the ventilator reverts to ventilation in the original support mode and at the original settings.

8.13 NIV

The NIV (Non Invasive Ventilation) is implementations of noninvasive positive pressure ventilation (NPPV). NPPV can use as its patient interface a mask, mouthpiece, or helmet-type interface, rather than an invasive conduit such as an endotracheal tube.

Intended for actively breathing patients, noninvasive ventilation is provided through a nonvented or nonported mask interface. Because this open breathing circuit permits air to leak around the mask or through the mouth, the ventilator achieves and maintains the prescribed pressure by adjusting the inspiratory flow.

9 Maintenance

WARNING:

To reduce the risk of electric shock, power down the ventilator and disconnect it from AC power before cleaning or servicing it.

NOTE:

It is the user's responsibility to comply with the information provided in this chapter.

To ensure the safety and reliability of your ventilator, follow these maintenance procedures along with your own institutional policies for cleaning, disinfecting, and maintaining equipment. All the procedures in this manual are intended to be performed by the operator. For further maintenance, contact your service representative.

9.1 Cleaning, Disinfection and Sterilization

WARNING:

- Read the material safety data sheet for each cleaning agent.
- Wear gloves and safety glasses. A damaged O2 sensor can leak and cause burns (contains potassium hydroxide).
- Reuse of undisinfected reusable accessories or components may cause cross-contamination.

NOTE:

- Keep all liquids away from electronic parts.
- After cleaning and disinfection is completed, run system check before using the ventilator. Use the ventilator only when system check is passed.
- The expiration valve assembly, inspiration safety valve assembly, and patient hose of the gas pathways through the ventilator can become contaminated with body fluids and expired gases during both NORMAL CONDITION and SINGLE FAULT CONDITION.

Ventilator exterior

Use a soft, moist, lint-free cloth to clean the outside surfaces of the ventilator.

The following cleaning agents are acceptable for use:

- Water
- Hydrogen peroxide (3%)

- Soapy water or mild detergent
- 70% isopropyl alcohol
- Germicidal disposable cloth (alkyl dimethyl benzyl ammonium chloride 0.07%; alkyl dimethyl ethybenzyl ammonium chloride 0.07%, remaining inert ingredients)
- Ammonium cleaner disinfectant
- Ethyl alcohol (75%)

Touchscreen

Dampen a soft cloth with isopropyl alcohol or a nonabrasive glass cleaner and wipe the screen. Avoid using cleaners other than glass cleaners. Do not use any vinegar-based solutions. Avoid using gritty cloths. Handle the touchscreen with care. To facilitate cleaning the touchscreen during ventilation, use the **Screen Lock** function.

Inspiration valve assembly and expiratory valve assembly

The following cleaning agents are acceptable for use:

- Water
- Alkalescent detergent (soap water etc.)

The following disinfection agents are acceptable for use:

- Medium- or high-efficiency detergent (alcohol or isopropyl alcohol etc.)
- Steam autoclave at maximum 134℃（recommend for more than 20 minutes）

HEPA filter and Air intake filter

The following cleaning agents are acceptable for use:

- Water
- Alkalescent detergent (soap water etc.)
- Medium- or high-efficiency detergent (alcohol or isopropyl alcohol etc.)

Reusable patient circuit

The recommended interval for cleaning and disinfection is each patient or weekly.

The following cleaning agents are acceptable for use:

- Water (flush)
- Alkalescent detergent (soap water etc.).
- Water temperature 40ºC (immersed for approximately three minutes).

The following disinfection agents are acceptable for use:

- Medium- or high-efficiency detergent (alcohol or isopropyl alcohol etc.)
- Steam autoclave at maximum 134℃ （recommend for more than 20 minutes）

Masks and other accessories

Follow the manufacturer's guidelines.

9.2 Preventive Maintenance

WARNING:

- To prevent patient or ventilator contamination, inspect and replace the main flow bacteria filter between patients and at regular intervals (or as stated by the manufacturer).
- To prevent possible patient injury, inspect and verify the proper operation of the exhalation port regularly during use.

CAUTION:

- Because some environments cause a quicker collection of lint and dust than others, inspect the filters more often when needed. The air inlet filter should be replaced; the cooling fan filter should be cleaned.
- To ensure proper system performance, use a aXcent-approved air inlet filter.

Perform preventive maintenance on the ventilator according to the schedule in Table 9.1. The following subsections provide details for some of these preventive maintenance procedures.

Table 9.1 Schedule of preventive maintenance

Interval	Part/accessory	Procedure
Each patient or as necessary	Breathing circuit (including mask, inspiratory filter, Flow Sensor, nebulizer jar, expiratory valve cover and membrane).	Replace with sterilized or new single use parts. Run the tightness test and the Flow Sensor calibration.

Interval	Part/accessory	Procedure
	Entire ventilator.	Run the system self-check.
Every day or as necessary	Breathing circuit.	Empty any water from breathing tubes or water traps. Inspect parts for damage. Replace as necessary.
Every month or as necessary	Air intake dust filters and fan filter	Check for dust and lint. If needed, clean or replace.
Every 6 months	Batteries	Recharge batteries by plugging ventilator into ac power source for at least 2 hours.
Yearly or every 5000h, or as necessary	Oxygen cell.	Replace if depleted.
	Air intake HEPA filter.	Replace.
	Ventilator.	Perform service-related preventive maintenance.
	Gas source sealing ring	Check the gas source sealing ring. Contact service personnel for replacement when necessary.
Every 30,000h	Turbine	Replace.
Every 4 years (30,000h)	Ventilator	Perform service-related preventive maintenance.
Every 6 years or as necessary	Battery of the clock module	Replace the battery of the clock module. Contact service personnel for replacement.

9.3 Disposal

Dispose of all parts removed from the device according to your institution's protocol.

Follow all local, state, and federal regulations with respect to environmental protection, especially when disposing of the electronic device or parts of it (for example, oxygen cell, batteries).

9.4 Storage

To maintain the battery charge and to prolong the life of the batteries, keep the ventilator connected to its primary power source. Have the batteries recharged every 6 months, depending on storage conditions (see Chapter 10 Specifications).

9.5 Repacking and Shipping

If you must ship the ventilator, use the original packing materials. If these materials are not available, contact your aXcent representative for replacement materials.

9.6 Battery Maintenance

CAUTION： The batteries can only be charged by this ventilator.

NOTE：

- Use batteries at least once every month to extend their life. Charge the batteries before they are depleted.
- Inspect and replace batteries regularly. Battery life depends on how frequent and how long it is used. For a properly maintained and stored lithium battery, its life expectancy is approximately 2 years. For more aggressive use models, life expectancy can be shortened. We recommend replacing lithium batteries every 2 years.
- In case of battery failure, contact service personnel replace it. Do not replace the battery without permission.

The ventilator is designed to operate on battery power whenever external power supply becomes interrupted. When the ventilator is connected to the external power source, the batteries are charged regardless of whether or not the ventilator is currently on. In case of power failure, the ventilator will automatically be powered by the internal batteries. When external power source is restored within the specified time, power supply is switched from battery to external power supply automatically to ensure continuous system use.

The battery icon displayed on the screen indicates the battery statuses as follows:

- indicates the capacity of the battery is 85%-100%.
- indicates the capacity of the battery is 65%-84%.
- indicates the capacity of the battery is 30%-64%.
- indicates the capacity of the battery is 0%-29%.
- indicates the battery is charging.

If the battery capacity is too low, the alarm “Battery low” will be triggered. In this case, apply external power to the ventilator.

Battery Use Guidance

Inspect and replace batteries regularly. Battery life depends on how frequent and how long it is used. For a properly maintained and stored lithium battery, its life expectancy is approximately 2 years. For more aggressive use models, life expectancy can be shortened.

We recommend replacing lithium batteries every 2 years.

To ensure maximum battery capacity:

- Check battery performance once every six months. Checking battery performance is also required before ventilator repair is carried out or when battery is doubted to be the source for ventilator failure.
- Condition batteries once every time when they have been

Battery Performance Checking

NOTE:

- If the running time of the battery is too short after fully charged, the battery may be damaged already or defective.
- If obvious signs of damage are detected on the battery or the battery recharging is failed, replace the battery and recycle it properly.

Check battery performance once every six months. Checking battery performance is also required before ventilator repair is carried out or when battery is doubted to be the source for ventilator failure. Battery performance may degrade over time.

Follow the below steps to check battery performance:

1. Disconnect the patient from the ventilator and shut down the ventilator.

2. Connect the ventilator to the external power source and charge the batteries uninterruptedly for at least 10 hours.
3. Disconnect the external power source. Allow the ventilator to operate on battery power until the ventilator shuts off.
4. The running time of the battery reflects its performance.

If the running time of the battery is noticeably shorter than that stated in the specifications, contact the service personnel to replace the battery.

Battery Performance Conditioning

NOTE：

- Condition batteries every time when they have been used for three months or when the battery running time becomes noticeably shorter.
- Over time and with the use of the battery, the actual battery capacity will decrease. For an old battery, the battery full icon does not indicate that the battery capacity or battery running time still meets the requirement specified. When conditioning batteries, replace the battery when its running time becomes noticeably shorter.

Condition batteries when they are put into use for the first time. A complete battery conditioning cycle is: uninterrupted charging, followed by uninterrupted discharging until the ventilator shuts off, and then uninterrupted charging. Condition batteries regularly to maintain their service life. Follow the below steps to condition batteries:

1. Disconnect the patient from the ventilator and shut down the ventilator.
2. Connect the ventilator to the external power source and charge the batteries uninterruptedly for at least 10 hours.
3. Disconnect the external power source. Allow the ventilator to operate on battery power until the ventilator shuts off.
4. Re-connect the ventilator to the external power source and charge the batteries uninterruptedly for at least 10 hours.

Battery Storage

If the ventilator is not used for a long time, contact service personnel to remove the batteries from the ventilator. Failure to do so will over-discharge the batteries and extend the battery charging

time noticeably. Not fully charge the batteries once every 2 months and keep battery power at 40-60%. Fully charge the batteries before use.

When storing batteries, make sure the battery electrodes do not get in touch with metal goods. In case of long-time storage, place batteries in a cool environment and keep battery power at 40-60%.

Placing batteries in a cool environment can delay battery aging. Ideally, batteries should be stored in a cool environment of 15℃ (60℉). Do not store batteries outside the environmental range of -20℃ (-4℉) to +60℃ (140℉).

10 Specifications

10.1 Physical Characteristic

Table 10.1 Physical Characteristic

Parameter	Specification
Dimensions (L*W*H)	310 mm * 323 mm * 400 mm 505 mm * 676 mm * 1380 mm (with trolley)
Weight	Approximately 9.9 kg Approximately 21 kg (with trolley)
Screen	Size: 13.1 TFT color touch screen Resolution: 1080*1920

10.2 Environmental Requirements

Table 10.2 Environment Requirement

Parameter	Specification
Temperature	Operating: 5 to 40°C (41 to 104°F) Storage: -20 to 60°C (-4 to 140°F)
Relative humidity	Operating: 10 to 95%, non-condensing Storage: 10 to 95%, non-condensing
Altitudes	Operating: 62 ~ 106 kPa Storage: 50 ~ 106 kPa

10.3 Electrical Specifications

Table 10.3 Electrical Specification

Parameter	Specification
Input power	AC voltage 100 to 240 V AC frequency 50 to 60 Hz AC current 2.5 to 1.1 A Fuse T2.5AH/250V
Batteries	Number: One or Two (Optional) Type: Lithium-ion Voltage: 11.25 V Volume: 6400 mAh (for a single battery) Max. Charge Voltage: 13.05 V Recharge Time: 4.5 hours (for a single battery) Operating Time: 3 hours under standard working condition

NOTE:

The standard working condition of the ventilator is as below:

Ventilation mode: PCV.

Control Settings: △Pinsp 15cmH2O / f 10bpm / Tinsp 2s / PEEP 5cmH20 / O2 21%.

10.4 Pneumatic Specifications

Table 10.4 Pneumatic Specification

Parameter	Specification
High-pressure oxygen inlet	Pressure:280 to 600KPa/41 to 87 psi/ 2.8 to 6.0 bar; Flow: ⩾120L/min (STPD)
Low-pressure oxygen inlet	Pressure: < 100KPa/1bar/14.5psi Flow: ⩽15L/min (STPD)
Air supply	Integrated turbine
Inspiratory outlet (To patient port)	Coaxial 15 mm/22 mm conical connector
Expiratory outlet (From patient port)	Coaxial 15 mm/22 mm conical connector
Compliance	Adult disposable circuit (including inspiratory safety valve, adult disposable breathing tubes, water trap, expiration valve): ⩽4ml/cmH2O; Adult reusable circuit ((including inspiratory safety valve, adult reusable breathing tubes, water trap, expiration valve, Y piece): ⩽2ml/cmH2O; Pediatric disposable circuit (including inspiratory safety valve, pediatric disposable breathing tubes, water trap, expiration valve):⩽2 ml/cmH2O; Pediatric reusable circuit ((including inspiratory safety valve, pediatric reusable breathing tubes, water trap, expiration valve, Ypiece): ⩽2 ml/cmH2O

Parameter	Specification
Inspiratory resistance	Not greater than 6 cm H2O at 60 L/min flow (adult reusable breathing tube) Not greater than 6 cmH2O at 30 L/min flow (pediatric reusable breathing tube)
Expiratory resistance	Not greater than 6 cm H2O at 60 L/min flow (adult reusable breathing tube) Not greater than 6 cmH2O at 30 L/min flow (pediatric reusable breathing tube)
Leakage	Not greater than 200mL/min@50cmH2O(adult tubes) Not greater than 100mL/min@40cmH2O(pediatric tubes)
Bacteria filter	Resistance: < 2 cmH2O at 60 l/min Particle size: Captures particles of 0.3 mm (micron) with > 99.99% efficiency Dead space：< 80 ml
Pneumatic medicament Nebulizer	Synchronous with inspiration at 6 to 9 L/min flow

10.5 Control Settings

Table 10.5.1 Control Settings

Parameter	Range	Resolution
O2%	21%~100%	1%
VT	Adult: 100~2000 ml Pediatric: 20~300 ml	Adult: 10 ml Pediatric: 1 ml
f	1~100 bpm	1 bpm

Parameter	Range	Resolution
fSIMV	1~60 bpm	1 bpm
PEEP	OFF, 1~40 cmH2O	1 cmH2O
ΔPinsp	5~60 cmH2O	1 cmH2O
ΔPsupp	0~60 cmH2O	1 cmH2O
Tinsp	0.2~10 s	0.05 s
I:E	1:10~4:1	1:2
Tslope	0~2 s	0.05 s
Phigh	0~60 cmH2O	1 cmH2O
Plow	0~45 cmH2O	1 cmH2O
Thigh	0.2~30 s	0.1 s
Tlow	0.2~30 s	01 s
Trigger	-10 ~ -0.5 cmH2O 0.5~15 L/min	0.5 cmH2O 0.1 L/min
Exp%	Auto, 10%~85%	5%
Apnea Vent	On, Off	/
ΔPapnea	5~60 cmH2O	1 cmH2O
fapnea	1~80 bpm	1 bpm
VTapnea	Adult: 100~2000 ml Pediatric: 20 ~300 ml	Adult: 10 ml Pediatric: 1 ml

Parameter	Range	Resolution
Apnea Tinsp	0.2~10 s	0.05 s
Assist	On, Off	/
Sigh	On, Off	/
Sigh Interval	2 s~180 min	1 min
Sigh Cycle	1~20	1
⊿int.PEEP	0~45 cmH2O	1 cmH2O
Tpause	OFF, 5~60%	1%
CPAP	4~25 cmH2O	1 cmH2O
EPAP	4~25 cmH2O	1 cmH2O
IPAP	4~25 cmH2O	1 cmH2O
Rise	1~5	1
Ramp	OFF, 5~45 min	1 min
Max P (VS maximum IPAP)	6~40 cmH2O	1 cmH2O
Min P (VS minimum IPAP)	4~25 cmH2O	1 cmH2O
Max P (PPV maximum pressure limit)	5~40 cmH2O	1 cmH2O

Parameter	Range	Resolution
Max V (PPV maximum volume limit)	200~3500 ml	5 ml
Max E	0~100 cmH2O/L	1 cmH2O/L
Max R	0~50 cmH2O/L/s	1 cmH2O/L/s
PPV%	0~100%	1%
Continuous Flow (O2 Therapy)	0-60 L/min	1 L/min
O2 Concentration (O2 Therapy)	21%~100%	1%

Table 10.5.2 Control Settings Accuracy

Parameter	Accuracy
O2%	Dual-limb: ±(3 vol.% +1% of setting)
	Single-limb: ±(5 vol.% +1% of setting)
VT	±(10 mL +10% of setting)
f	±1 bpm
fSIMV	±1 bpm
Tinsp	±0.1s or ±10% of setting, whichever is greater
I: E	2: 1 to 1: 4: ±10% of setting Other range: ±15% of setting
Tslope	±（0.2s+20% of setting）
PEEP	±(2.0 cmH2O + 5% of setting)

Parameter	Accuracy
△Pinsp	±(2.0 cmH2O + 5% of setting)
△Psupp	±(2.0 cmH2O + 5% of setting)
Phigh	±(2.0 cmH2O + 5% of setting)
Plow	±(2.0 cmH2O + 5% of setting)
Thigh	±0.2s or ±10% of setting, whichever is greater
Tlow	±0.2s or ±10% of setting, whichever is greater
Trigger	±(1.0 cmH2O + 10% of setting) ±(1.0 L/min + 10% of setting)
△int.PEEP	±(2.0 cmH2O + 5% of setting)
Exp%	±10%
fapnea	±1 bpm
△Papnea	±(2.0 cmH2O + 5% of setting)
VTapnea	±(10 mL +10% of setting)
Apnea Tinsp	±0.1s or ±10% of setting, whichever is greater
Tpause(%)	±0.1s or ±10% of setting, whichever is greater
CPAP	±(2.0 cmH2O + 5% of setting)
EPAP	±(2.0 cmH2O + 5% of setting)
IPAP	±(2.0 cmH2O + 5% of setting)
Rise	/
Ramp Time	±1 s

Parameter	Accuracy
Max P (VS maximum IPAP)	±(2.0 cmH2O + 5% of setting)
Min P (VS minimum IPAP)	±(2.0 cmH2O + 5% of setting)
Max P (PPV maximum pressure limit)	±(2.0 cmH2O + 5% of setting)
Max V (PPV maximum volume limit)	±15%
Max E	/
Max R	/
Continuous Flow (O2 Therapy)	±(2 L/min+10% of setting)
O2 Concentration (O2 Therapy)	±(3 vol.% +1% of setting)

Table 10.5.3 Control Settings Configuration

Parameter	Model
	c
O2%	√
VT	√
f	√
fSIMV	√
PEEP	√
ΔPinsp	√
ΔPsupp	√
Tinsp	√
I:E	√

Parameter	Model
	c
Tslope	√
Phigh	√
Plow	√
Thigh	√
Tlow	√
Trigger	√
Exp%	√
Apnea Vent	√
ΔPapnea	√
fapnea	√
VTapnea	√
Apnea Tinsp	√
Assist	√
Sigh	√
Sigh Interval	√
Sigh Cycle	√
Δint.PEEP	√
Tpause	√
CPAP	√
EPAP	√

Parameter	Model
	c
IPAP	√
Rise	√
Ramp	√
Max P (VS maximum IPAP)	√
Min P (VS minimum IPAP)	√
Max P (PPV maximum pressure limit)	√
Max V (PPV maximum volume limit)	√
Max E	√
Max R	√
PPV%	√
Continuous Flow (O2 Therapy)	√
O2 Concentration (O2 Therapy)	√

10.6 Monitored Parameters

Table 10.6.1 Monitored Parameters

Parameter	Range	Resolution	Accuracy
Paw	0~100 cmH2O	1 cmH2O	± (2 cmH2O + 4 % of actual reading)
Ppeak	0~100 cmH2O	1 cmH2O	± (2 cmH2O + 4 % of actual reading)
Pplat	0~100 cmH2O	1 cmH2O	± (2 cmH2O + 4 % of actual reading)
Pmean	0~100 cmH2O	1 cmH2O	± (2 cmH2O + 4 % of actual reading)
PEEP	0~100 cmH2O	1 cmH2O	± (2 cmH2O + 4 % of actual reading)
MV	0~99.9 L/min	0.1 L/min	±8 % of actual reading or ± 0.3 L/min whichever is greater
MVleak	0~99.9 L/min	0.1 L/min	±8 % of actual reading or ± 0.3 L/min whichever is greater
MVspn	0~99.9 L/min	0.1 L/min	±8 % of actual reading or ± 0.3 L/min whichever is greater
VTe	0~100 mL	1 mL	±(10 ml + 3% of the actual reading)
	100~4000 mL		±(3 mL + 10% of the actual reading)
VTi	0~100 mL	1 mL	±(10 ml + 3% of the actual reading)
	100~4000 mL		±(3 mL + 10% of the actual reading)
VTe spn	0~100 mL	1 mL	±(10 ml + 3% of the actual reading)

Parameter	Range	Resolution	Accuracy
	100~4000 mL		±(3 mL + 10% of the actual reading)
VTe/IBW	0~100 mL	1 mL	±(10 ml + 3% of the actual reading)
	100~4000 mL		±(3 mL + 10% of the actual reading)
ftotal	0~200 bpm	1 bpm	±5 % of actual reading or ±1bmp, whichever is greater
fmand	0~200 bpm	1 bpm	±5 % of actual reading or ±1bmp, whichever is greater
fspn	0~200 bpm	1 bpm	±5 % of actual reading or ±1bmp, whichever is greater
Re	0~600 cmH2O/L/s	1 cmH2O/L/s	0~50cmH2O/(L/s): ±10cmH2O/(L/s) Other range: /
Ri	0~600 cmH2O/L/s	1 cmH2O/L/s	0~50cmH2O/(L/s): ±10cmH2O/(L/s) Other range: /
Cdyn	0~300 ml/cmH2O	1 ml/cmH2O	0~100ml/cmH2O: ±20 % of actual reading or ±10 ml/cmH2O, whichever is greater Other range: /
Cstat	0~300 ml/cmH2O	1 ml/cmH2O	0~100ml/cmH2O: ±20 % of actual reading or ±10 ml/cmH2O, whichever is greater Other range: /
Rcexp	0~10.0 s	0.01 s	/
WOB	0~100 J/min	1 J/min	/

Parameter	Range	Resolution	Accuracy
RSBI	0~999 1/(min·L)	1 1/(min·L)	0~1000 1/(min·L): ±15 % of actual reading or ±20 1/(min·L), whichever is greater
NIF	-45~0 cmH2O	0.1 cmH2O	± (2 cmH2O + 4% of the actual reading)
P0.1	-20~0 cmH2O	0.1 cmH2O	± (2 cmH2O + 4% of the actual reading)
PEEPi	0~100 cmH2O	1 cmH2O	/
PIP	0-50 cmH2O	1 cmH2O	± (2 cmH2O + 4 % of actual reading)
EPAP	0-50 cmH2O	1 cmH2O	± (2 cmH2O + 4 % of actual reading)
MV	0~99.9 L/min	0.1 L/min	±8 % of actual reading or ± 0.3 L/min whichever is greater
VT	0~3000 mL	1 mL	± (4 mL + 10% of the actual reading)
f	0~200 bpm	1 bpm	±5 % of actual reading or ±1bmp, whichever is greater
Pt.leak	0~200 L/min	0.1 L/min	/
Pt.Trig	0~100%	1%	±10 %
Tot.leak	0~200 L/min	0.1 L/min	/
Ti/Ttot	0~91%	1%	±5 %

Parameter	Range	Resolution	Accuracy
FiO2	15~100 %	1%	±(2.5 vol. % + 2.5% of the actual reading) The responded time of the oxygen concentration in the delivered volume to change from a volume fraction of 21 % to 90 % of the maximum settable oxygen concentration: ≤ 45 s.
Continuous Flow (O2 Therapy)	0~60 L/min	0.1 L/min	±8 % of actual reading or ± 0.3 L/min whichever is greater

Table 10.6.2 Monitored Parameters Configuration

Parameter	Model
Paw	√
Ppeak	√
Pplat	√
Pmean	√
PEEP	√
Insp Flow	√
Exp Flow	√
MV	√
MVleak	√
MVspn	√
VTe	√

Parameter	Model
VTi	√
VTe spn	√
VTe/IBW	√
ftotal	√
fmand	√
fspn	√
Re	√
Ri	√
Cdyn	√
Cstat	√
Rcexp	√
WOB	√
RSBI	√
NIF	√
P0.1	√
PEEPi	√
PIP	
EPAP	
Pt.leak	
Pt.Trig	

Parameter	Model
Tot.leak	
Ti/Ttot	
FiO2	√
Continuous Flow (O2 Therapy)	√

10.7 Alarms

Table 10.7.1 Alarms Settings (LYRA x2)

Alarms		Range
Paw	High Limit	10~85 cmH2O
MV	High Limit	Adult: Low Limit＋0.1~100 L/min
		Pediatric: Low Limit＋0.1~60 L/min
	Low Limit	Pediatric: 0.1~ (High Limit－0.1) or 30.0, whichever is smaller
		Adult: 0.1~ (High Limit－0.1) or 50.0, whichever is smaller
VTe	High Limit	Adult: off, (Low Limit +10 or 110 whichever is greater) ~4000
		Pediatric: off, Low Limit +10 or 25 whichever is greater ~600
	Low Limit	Adult: off, 50 ~ (High Limit -10) mL
		Pediatric: off, 10 ~ (High Limit -10) mL
ftotal	High Limit	Adult / Pediatric: off, 1~150 bpm
Tapnea	High Limit	Adult / Pediatric: 5~60 s
FiO2 (Low-pressure oxygen)	High Limit	Adult / Pediatric: (Low Limit +2) ~100 %
	Low Limit	Adult / Pediatric: 18 ~ (High Limit -2) %

Table 10.7.2 Alarms Settings (LYRA x2 b)

Alarms		Range
Inspiratory Pressure	High Limit	Adult / Pediatric: (Low Limit +2) ~ 50 cmH2O
	Low Limit	Adult / Pediatric: Off, 1 ~ (High Limit -2) cmH2O
MV	Low Limit	off, 1~99 L/min
VT	High Limit	Adult / Pediatric: (Low Limit +10) ~ 2500 mL
	Low Limit	Adult / Pediatric: off, 5 ~ (High Limit -10) mL
f	High Limit	Adult / Pediatric: (Low Limit +2) ~ 90 bpm
	Low Limit	Adult / Pediatric:1 ~ (High Limit -2) bpm
LIPT (Low Inspiratory Pressure Delay Time)	Low Limit	Adult / Pediatric:5~60 s

10.8 Configuration Specifications

Table 10.8.1 Feature Specifications

Features		Model		
		a	b	c
Ventilation Mode	CPAP (Continuous Positive Airway Pressure)	√	√	
	PCV (Pressure Control Ventilation)	√	√	√
	PPS (Proportional Pressure Support)	√	√	
	S/T (Spontaneous/Timed)	√	√	
	VS (Volume Support)	√	√	
	VCV (Volume Control Ventilation)	√		√
	VSIMV (Volume Synchronized Intermittent Mandatory Ventilation)	√		√
	PSIMV (Pressure Synchronized Intermittent Mandatory Ventilation)	√		√
	PRVC (Pressure Regulated Volume Control)	√		√
	V^{+}SIMV (PRVC + SIMV)	√		√

Features		Model		
		a	b	c
	CPAP/PSV (Continuous Positive Airway Pressure/Pressure Support Ventilation)	√		√
	BPAP (Bilevel Positive Airway Pressure)	√		√
	APRV (Airway Pressure Release Ventilation)	√		√
Therapy Mode	Oxygen Therapy	√	√	√
Monitoring	Waveform	√	√	√
	Numeric	√	√	√
	Loop	√	√	√
	Trend	√	√	√
Special Functions	NIV （Non Invasive Ventilation）			√
	Apnea Ventilation	√	√	√
	STRC (Synchronized Tube Resistance Compensation)	√		√
	O2 Enrichment	√		√
	Suction Tool	√		√
	Nebulization	√		√
	Manual breath	√		√
	Inspiratory Hold	√		√
	Expiratory Hold	√		√
	P0.1 (Airway Occlusion Pressure)	√		√
	NIF (Negative Inspiratory Force)	√		√
	PEEPi (Intrinsic PEEP)	√		√

Table 10.8.2 System Configuration

Items	Range
Screen brightness	0-100%
Tinsp/I:E	Tinsp , I:E
Height/IBW	Height , IBW
IV Apnea Mode	Pressure Control
VT/IBW	6mL/kg , 7mL/kg , 8mL/kg , 9mL/kg , 10mL/kg , 11mL/kg , 12mL/kg
O2 Monitoring	ON / OFF
System Date	/
System Time	/
Date Format	YYYY-MM-DD, MM-DD-YYYY, DD-MM-YYYY
Time Format	12h, 24h

10.9 Factory Default Settings

Table 10.9.1 Ventilation Mode Settings

Mode	Parameter	Factory Default Settings
VCV	VT	Adult: max(7*mL/kg*IBW, 100) Pediatric: 7*mL/kg*IBW
	O2% (HPO)	21%
	f	Adult: 10 bpm Pediatric: 20 bpm
	PEEP	3 cmH2O
	Tinsp	Adult: 2.00 s Pediatric: 1.00 s

Mode	Parameter	Factory Default Settings
	I:E	1:2
	Tslope	0.2 s
	F-Trigger	Adult: 2.0 L/min Pediatric: 1.0 L/min
	Assist	ON
	Sigh	OFF
	Sigh Interval	1 min
	Sigh Cycles	3
	Δint.PEEP	5cmH2O
	Tpause	OFF
PCV (INV)	O2% (HPO)	21%
	f	Adult: 10 bpm Pediatric: 20 bpm
	PEEP	3 cmH2O
	ΔPinsp	15 cmH2O
	Tinsp	Adult: 2.00 s Pediatric: 1.00 s
	I:E	1:2
	Tslope	0.2 s
	F-Trigger	Adult: 2.0 L/min Pediatric: 1.0 L/min
	Assist	ON
	Sigh	OFF
	Sigh Interval	1 min

Mode	Parameter	Factory Default Settings
	Sigh Cycles	3
	Δint.PEEP	5 cmH2O
CPAP/PSV	O2% (HPO)	21%
	PEEP	3 cmH2O
	ΔPsupp	0 cmH2O
	Tinsp (Only in NIV mode)	Adult: 2.00 s Pediatric: 1.00 s
	Tslope	0.2 s
	F-Trigger	Adult: 2.0 L/min Pediatric: 1.0 L/min
	Exp%	Auto
	Δpapnea	15 cmH2O
	fapnea	1 bpm
	Apnea Tinsp	Adult: 2.00 s Pediatric: 1.00 s
	VTapnea	Adult: max(7*mL/kg*IBW, 100) Pediatric: 7*mL/kg*IBW
PSIMV	O2% (HPO)	21%
	fSIMV	Adult: 5 bpm Pediatric: 20 bpm
	PEEP	3 cmH2O
	ΔPinsp	15 cmH2O
	ΔPsupp	0 cmH2O
	Tinsp	Adult: 2.00 s Pediatric: 1.00 s

Mode	Parameter	Factory Default Settings
	Tslope	0.2 s
	F-Trigger	Adult: 2.0 L/min Pediatric: 1.0 L/min
	Exp%	Auto
	Δpapnea	15 cmH2O
	fapnea	1 bpm
	Apnea Tinsp	Adult: 2.00 s Pediatric: 1.00 s
	VTapnea	Adult: max(7*mL/kg*IBW, 100) Pediatric: 7*mL/kg*IBW
	Apnea Vent	ON
	Sigh	OFF
	Sigh Interval	1 min
	Sigh Cycles	3
	Δint.PEEP	5 cmH2O
VSIMV	VT	Adult: max(7*mL/kg*IBW, 100) Pediatric: 7*mL/kg*IBW
	O2% (HPO)	21%
	fSIMV	Adult: 5 bpm Pediatric: 20 bpm
	PEEP	3 cmH2O
	ΔPsupp	0 cmH2O
	Tinsp	Adult: 2.00 s Pediatric: 1.00 s
	Tslope	0.2 s

Mode	Parameter	Factory Default Settings
	F-Trigger	Adult: 2.0 L/min Pediatric: 1.0 L/min
	Exp%	Auto
	Δpapnea	15 cmH2O
	fapnea	1 bpm
	Apnea Tinsp	Adult: 2.00 s
	VTapnea	Adult: max(7*mL/kg*IBW, 100) Pediatric: 7*mL/kg*IBW
	Apnea Vent	ON
	Sigh	OFF
	Sigh Interval	1 min
	Sigh Cycles	3
	Δint.PEEP	5 cmH2O
	Tpause	OFF
V+SIMV	VT	Adult: max(7*mL/kg*IBW, 100) Pediatric: 7*mL/kg*IBW
	O2% (HPO)	21%
	fSIMV	Adult: 5 bpm Pediatric: 20 bpm
	PEEP	3 cmH2O
	ΔPsupp	0 cmH2O
	Tslope	0.2 s
	F-Trigger	Adult: 2.0 L/min
	Exp%	Auto

Mode	Parameter	Factory Default Settings
	Δpapnea	15 cmH2O
	fapnea	1 bpm
	Apnea Tinsp	Adult: 2.00 s
	VTapnea	Adult: max(7*mL/kg*IBW, 100) Pediatric: 7*mL/kg*IBW
	Apnea Vent	ON
	Sigh	OFF
	Sigh Interval	1 min
	Sigh Cycles	3
	Δint.PEEP	5 cmH2O
BPAP	O2% (HPO)	21%
	ΔPsupp	0 cmH2O
	Tslope	0.2 s
	Phigh	15 cmH2O
	Plow	3 cmH2O
	Thigh	Adult: 1.7 s Pediatric: 0.7 s
	Tlow	Adult: 3.3 s Pediatric: 1.4 s
	F-Trigger	Adult: 2.0 L/min Pediatric: 1.0 L/min
	Exp%	Auto
	Δpapnea	15 cmH2O
	fapnea	1 bpm

Mode	Parameter	Factory Default Settings
	Apnea Tinsp	Adult: 2.00 s Pediatric: 1.00 s
	VTapnea	Adult: max(7*mL/kg*IBW, 100) Pediatric: 7*mL/kg*IBW
PRVC	VT	Adult: max(7*mL/kg*IBW, 100) Pediatric: 7*mL/kg*IBW
	O2% (HPO)	21%
	f	Adult: 10 bpm Pediatric: 20 bpm
	PEEP	3 cmH2O
	Tinsp	Adult: 2.00 s Pediatric: 1.00 s
	I:E	1:2
	Tslope	0.2 s
	F-Trigger	Adult: 2.0 L/min Pediatric: 1.0 L/min
	Assist	ON
	Sigh	OFF
	Sigh Interval	1 min
	Sigh Cycles	3
	Δint.PEEP	5cmH2O
APRV	O2% (HPO)	21%
	Tslope	0.2 s
	Phigh	15 cmH2O
	Plow	3 cmH2O

Mode	Parameter	Factory Default Settings
	Thigh	Adult: 1.7 s Pediatric: 0.7 s
	Tlow	Adult: 3.3 s Pediatric: 1.4 s
	F-Trigger	Adult: 2.0 L/min Pediatric: 1.0 L/min
	Δpapnea	15 cmH2O
	fapnea	1 bpm
	Apnea Tinsp	Adult: 2.00 s Pediatric: 1.00 s
	VTapnea	Adult: max(7*mL/kg*IBW, 100) Pediatric: 7*mL/kg*IBW
CPAP	O2% (HPO)	21%
	CPAP	4 cmH2O
	Rise	3
	Ramp	OFF
	Δpapnea	5 cmH2O
	fapnea	1 bpm
	Apnea Tinsp	Adult: 2.00 s Pediatric: 1.00 s
S/T	O2% (HPO)	21%
	f	Adult: 10 bpm Pediatric: 20 bpm
	Tinsp	Adult: 2.00 s Pediatric: 1.00 s
	I-Trigger	3

Mode	Parameter	Factory Default Settings
	E-Cycle	3
	IPAP	5 cmH2O
	EPAP	10 cmH2O
	Rise	3
	Ramp	OFF
PCV (NIV)	O2% (HPO)	21%
	f	Adult: 10 bpm Pediatric: 20 bpm
	Tinsp	Adult: 2.00 s Pediatric: 1.00 s
	IPAP	5 cmH2O
	EPAP	10 cmH2O
	Rise	3
	Ramp	OFF
VS	VT	Adult: max(7*mL/kg*IBW, 100) Pediatric: 7*mL/kg*IBW
	O2% (HPO)	21%
	f	Adult: 10 bpm Pediatric: 20 bpm
	I-Trigger	3
	E-Cycle	3
	EPAP	10 cmH2O
	Rise	3
	Min P	10 cmH2O

Mode	Parameter	Factory Default Settings
	Max P	10 cmH2O
PPS	O2% (HPO)	21%
	f	Adult: 10 bpm Pediatric: 20 bpm
	Tinsp	Adult: 2.00 s Pediatric: 1.00 s
	I-Trigger	3
	E-Cycle	3
	IPAP	5 cmH2O
	EPAP	10 cmH2O
	Rise	3
	Max P	20 cmH2O
	Max V	600 ml
	Max E	15 cmH2O/L
	Max R	4 cmH2O/L/s
	PPV%	50%

Table 10.9.2 O2 Therapy Settings

Parameter	Factory Default Settings
O2%	21%
Flow	25 L/min

Table 10.9.3 Alarms Settings

Alarms		Factory Default Settings
Paw	High Limit	50 cmH2O
MV	High Limit	VT Setting Value * f * 1.5 L/min
	Low Limit	VT Setting Value * f * 0.6 L/min
VTe	High Limit	VT Setting Value * 2
	Low Limit	VT Setting Value * 0.5
ftotal	High Limit	30 bpm
Tapnea	High Limit	15 s
FiO2 (Low-pressure oxygen)	High Limit	100 %
	Low Limit	21%
Inspiratory Pressure	High Limit	50 cmH2O
	Low Limit	OFF
VT	High Limit	2500 ml
	Low Limit	OFF
f	High Limit	30 bpm
	Low Limit	10 bpm
LIPT (Low Inspiratory Pressure Delay Time)	Low Limit	1 s

Table 10.9.4 System Configuration

Items	Factory Default Setting
Screen brightness	50%
Tinsp/I:E	Tinsp
Height/IBW	Height

IV Apnea Mode	Pressure Control
VT/IBW	7mL/kg
O2 Monitoring	ON
System Date	2017.01.01
System Time	00:00:00
Date Format	YYYY-MM-DD
Time Format	24h

A Ventilation Modes

VCV Mode

In **VCV** (Volume-Controlled Ventilation) mode, the patient receives the set tidal volume with every mandatory breath. The applied breathing volume is independent of changes in the lung mechanics.

The number of mandatory breath is defined by the respiratory rate. This means that the minute volume remains constant over time.

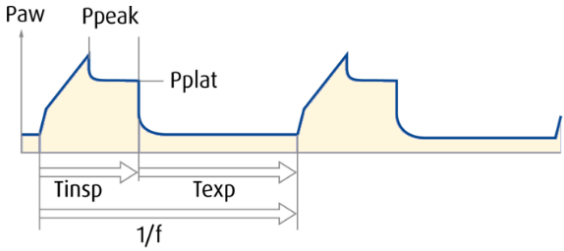


Figure A.1 VCV pressure waveform

PCV Mode

In **PCV** (Pressure-Controlled Ventilation) mode, the patient's tidal volume is determined by setting upper and lower pressure levels, and is dependent upon overall pulmonary compliance. The upper pressure level is maintained for the duration of inspiration.

The number of mandatory breaths is defined by the respiratory rate. The mandatory breaths are machine-triggered and not triggered by the patient.

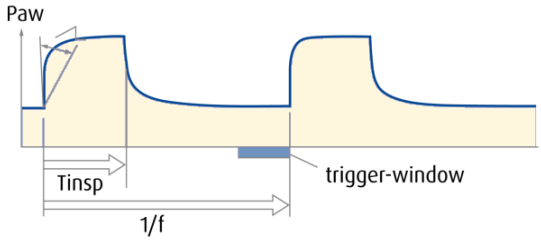


Figure A.2 PCV pressure waveform

VSIMV Mode

The **VSIMV** (Volume-controlled Synchronized Intermittent Mandatory Ventilation) mode is a combination of time-cycled, volume-controlled ventilation that allows spontaneous breathing to take place in between the set mandatory breaths. Mandatory breaths are delivered to stabilize oxygenation and reduce the work of breathing.

In this mode, the patient is supplied with the set tidal volume during the mandatory breaths. The mandatory breaths are synchronized with the patient's own breathing attempts. To prevent a mandatory breaths from being applied during spontaneous expiration, a patient-triggered mandatory breath can only be triggered within a trigger window. The patient can breathe spontaneously at PEEP level during the expiration phase. During spontaneous breathing at PEEP level, the patient can be pressure-supported using PS.

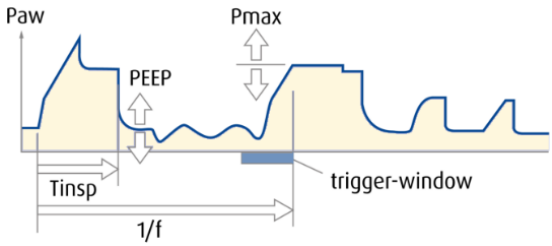


Figure A.3 VSIMV pressure waveform

PSIMV Mode

The **PSIMV** (Pressure-controlled Synchronized Intermittent Mandatory Ventilation) mode is a combination of time-cycled, pressure -controlled ventilation that allows spontaneous breathing to take place in between the set mandatory breaths. Mandatory breaths are delivered to stabilize oxygenation and reduce the work of breathing.

In this mode, the patient can breathe spontaneously at any time, but the number of mandatory breaths is specified. The mandatory breaths are synchronized with the patient’s own breathing attempts. A patient-triggered mandatory breath can only be triggered within a trigger window.

The mandatory tidal volume results from the pressure difference between PEEP and Pinsp, the lung mechanics and the breathing effort of the patient. During spontaneous breathing at PEEP level, the patient can be supported using PS.

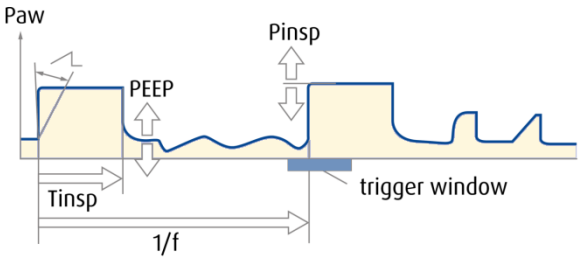


Figure A.4 PSIMV pressure waveform

BPAP Mode

The **BPAP** (Bilevel Positive Airway Pressure) mode is a combination of time-cycled and pressure-controlled ventilation that allows spontaneous breathing at both pressure levels. Usually delivered with pressure support for spontaneous breaths.

In this mode, the patient can breathe spontaneously at any time, but the number of mandatory breaths is specified. The mandatory breaths are synchronized with the breathing attempts of the patient both for inspiration and expiration. If the mandatory breath is shortened on account of the synchronization with expiration, the next mandatory breath is extended. The tidal volume delivered depends on the difference between the two pressure levels used, and on lung elasticity (compliance).

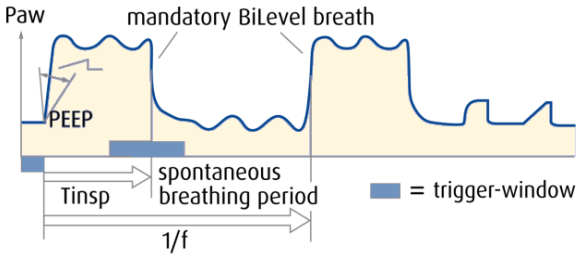


Figure A.5 BPAP pressure waveform

CPAP/PSV Mode

In **CPAP/PSV** (Continuous Positive Airway Pressure/Pressure Support Ventilation) mode, pressure support is delivered at a fixed pressure value to the spontaneously breathing patient. This partially replaces the patient's work of breathing and allows deeper breaths.

Every detected inspiration attempt at PEEP level triggers a patient-triggered, flow-cycled, pressure-supported mandatory breath. The point of time, the number and the duration of the pressure-supported breaths are determined by the patient.

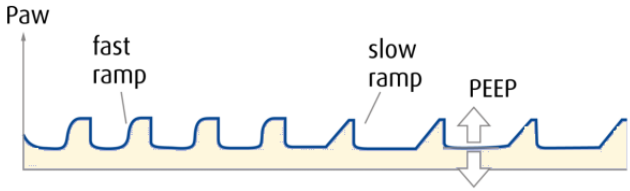


Figure A.6 CPAP/PSV pressure waveform

PRVC Mode

The **PRVC** (Pressure Regulated Volume Control Ventilation) mode delivers volume-targeted, time-cycled mandatory breaths and flow-cycled spontaneous breaths, and ensures that the set target volume is delivered during the mandatory breaths.

In this mode, spontaneous breathing at the lower pressure level can occur at the CPAP level or it can be pressure-supported. The machine is programmed using a desired target volume instead of using the upper pressure level (Pinsp). The machine delivers a breath every time the pressure changes from the lower pressure level (PEEP) to the upper pressure level (Pinsp). The exact level of pressure delivered depends on the set target volume, and on lung elasticity (compliance). A safe window is created (Pmax and Pmin), within which the upper pressure level adjusts freely on a breath-by-breath basis and at increments not exceeding 3 mbar.

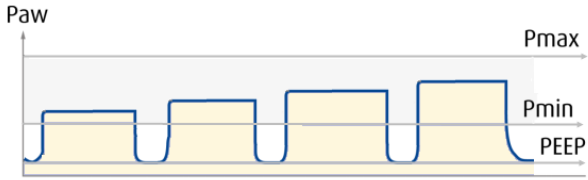


Figure A.7 PRVC pressure waveform

APRV Mode

The **ARPV** (Airway Pressure Release Ventilation) mode is a combination of time-cycled and pressure-controlled ventilation that allows spontaneous breathing to occur at the upper pressure level (IRV), which is usually maintained throughout a long inspiratory phase.

In this mode, to execute an active expiration, the pressure is reduced for the brief period Texp to Pexp. To support CO2 elimination, the pressure is reduced to Pexp for the brief period Texp. The alternation between the two pressure levels is machine-triggered and time cycled.

The breathing volume for APRV breath depends on lung compliance, respiratory resistance, the magnitude and duration of the pressure release and the magnitude of the patient's spontaneous breathing efforts.

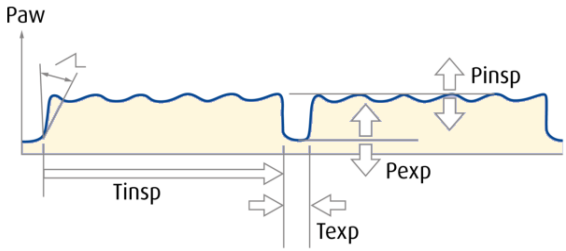


Figure A.8 APRV pressure waveform

CPAP Mode

The **CPAP (**Continuous Positive Airway Pressure**)** mode is a spontaneous breathing ventilation. The positive airway pressure is maintained throughout the ventilation cycle, but particularly during the expiratory phase (PEEP level).

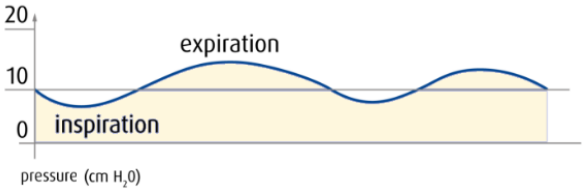


Figure A.9 CPAP pressure waveform

PPS Mode

In **PPS** (Proportional Pressure Support) mode, a patient-triggered flow-cycled pressure support is applied proportionally to the inspiration effort of the spontaneously breathing patient, i.e. a low breathing effort is only supported mildly, whereas a stronger breathing effort triggers a larger support. This partially replaces the patient's work of breathing and allows deeper breaths. The absolute level of the support depends both on the configuration of the parameters Flow Assist and Volume Assist and the patient.

The two types of pressure support, volume-proportional pressure support (volume assist) and flow-proportional pressure support (flow assist) can be used in combination. With volume assist, the elastic resistance can be compensated, whereas flow assist helps overcoming the airway resistance.

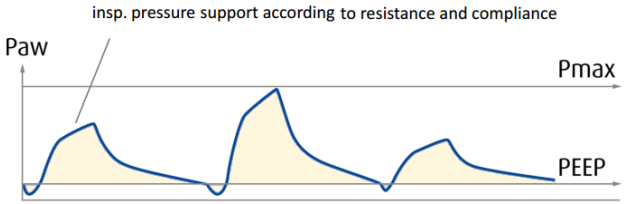


Figure A.10 PPS pressure waveform

S/T Mode

The **S/T** (Spontaneous/Timed) mode is a combination of time-cycled and pressure-controlled ventilation. In this mode, depending on the patient's spontaneous breathing activity during the set cycle time, either mandatory breaths are initiated or the patient is allowed to breathe spontaneously. Breath cycles are defined by setting a fixed respiratory rate. If the patient fails to breathe spontaneously during the cycle, the machine will initiate a conventional Bilevel breath at the end of the calculated cycle time.

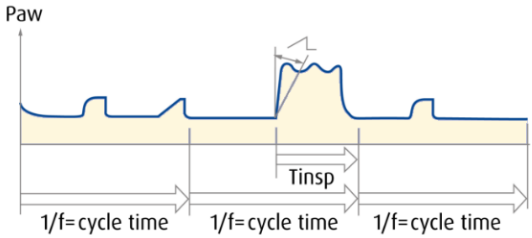


Figure A.11 S/T pressure waveform

VS Mode

In **VS** (Volume Support) mode, pressure support is delivered in a dynamic manner (for each breath, the level of pressure support delivered is adjusted to meet a set target volume) to the spontaneously breathing patient. This partially replaces the patient's work of breathing and allows deeper breaths. Every detected inspiration attempt at PEEP level triggers a pressure-supported, flow-cycled ventilation breath. If the lung mechanics change, the applied pressure varies to keep the set target volume constant. A safe window is created (Pmax and Pmin), within which the level of pressure support required adjusts freely on a breath-by-breath basis, at increments not exceeding 3 mbar.

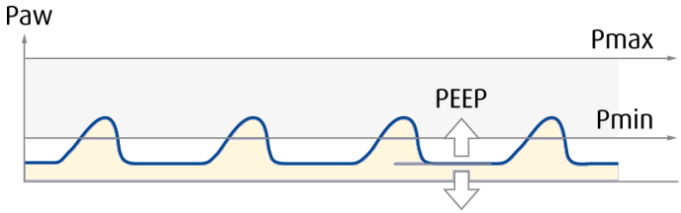


Figure A.12 VS pressure waveform

B Pneumatic Diagram

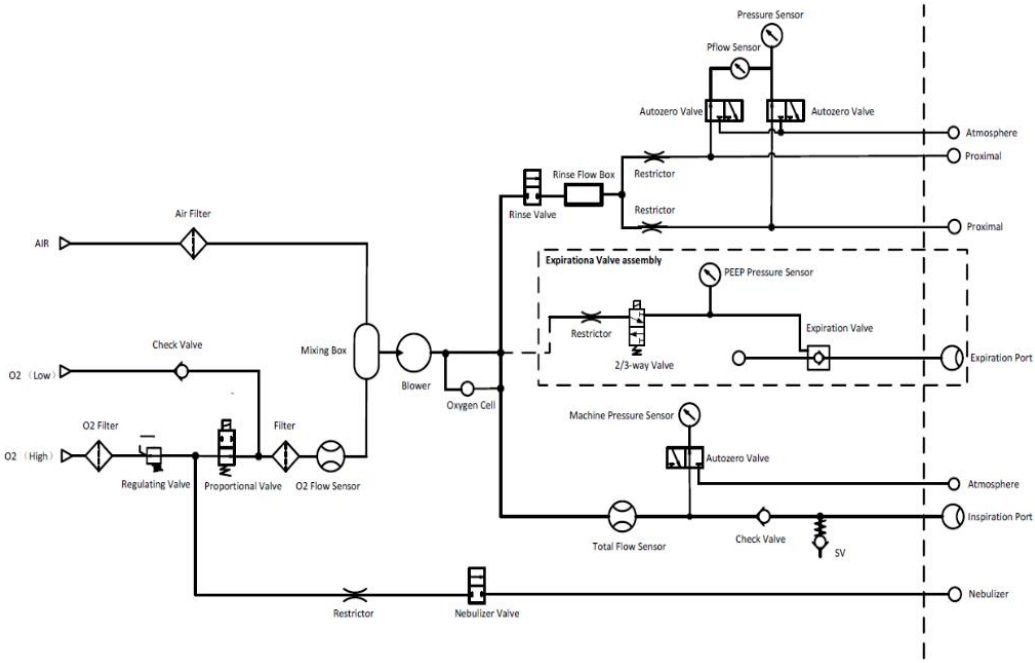


Figure B-1. Pneumatic diagram

C Parts and Accessories

WARNING:

- Use only accessories specified in this chapter. Using other accessories may cause incorrect measured values or equipment malfunction.
- Check the accessories and their packages for damage. Do not use them if any sign of damage is detected.
- Disposable accessories can not be reused. Reuse may degrade performance or cause cross infection of the next patient.
- Parts which are intended to contact patients must comply with the biocompatibility requirement of ISO10993-1 to prevent any adverse reactions arising from such contact. The duration of contact category should be less than 24 hours.
- Disposal of the accessories shall comply with the applicable waste control regulations.
- The user shall buy legally launched products for other accessories required to implement the functions of the machine.

Table C.1 Parts and Accessories

Description	Part No.	Manufacturer
Dual-limb breathing circuit package (Adult, Reusable)	5000-000040-00	VADI
Dual-limb breathing circuit package (Pediatric, Reusable)	5000-000041-00	VADI
Dual-limb breathing circuit package (Adult, Disposable)	5000-000042-00	VADI
Dual-limb breathing circuit package (Pediatric, Disposable)	5000-000043-00	VADI
Single-limb breathing circuit package (Adult, Disposable)	5000-000044-00	VADI
Flow Sensor, pediatric/adult, single-patient use (package of 10)	5000-000047-00	HAMILTON

Description	Part No.	Manufacturer
Inspiratory valve assembly, reusable	3600-000019-	aXcent
Expiratory valve assembly, reusable (Includes Membrane, expiratory valve, reusable)	3600-000009-00	aXcent
Inspiratory filter	5001-000004-00	Vincent medical
Artificial nose	5000-000038-00	Vincent medical
Humidifier (MR810/230V)	5000-000050-00	Fisher&Paykel
Humidifier (SH330/220V)	5000-000051-00	Ji Ke
Humidifier (SH330/110V)	5000-000052-00	Ji Ke
Face mask, size small	5000-000021-	BMC
Face mask, size medium	5000-000023-	BMC
Face mask, size Large	5000-000022-	BMC
Demonstration lung	5000-000039-00	Vincent medical
Clipped demonstration lung	5000-000046-	VADI
Air intake filter	5002-000004-	aXcent
HEPA filter	3600-000021-	aXcent
Oxygen supply hose assembly-NIST connector, European standard	5000-000048-00	GENTEC
Oxygen supply hose assembly-DISS connector, American standard	5000-000049-00	GENTEC
Oxygen cell	0022-000013-	RRC
Standard trolley	3600-000039-	aXcent

Description	Part No.	Manufacturer
Support arm, for standard trolley	5000-000038-	aXcent
Battery (standard/optional)	0502-000002-	ENVITEC
Power cord with US plug, 3-pin	0100-000012-	VOLEX
Power cord with British angled-plug	0100-000013-	VOLEX
Power cord with continental European plug, 3-pin	0100-000004-	VOLEX

D Communications Interface

HDMI Interface

The ventilator can output the video signals to an external monitor via HDMI interface.

RS-232 serial port

The ventilator can connect to the Nurse Call device via the RS-232 serial port.

USB Interface

The ventilator can transfer data via the external storage device via the USB interface.

E EMC Declarations

NOTE:

- Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the equipment.
- The ventilator or its components should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the ventilator or its components should be observed to verify normal operation in the configuration in which it will be used.
- The ventilator needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Other devices may interfere with this equipment even though they meet the requirements of CISPR.
- When the input signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
- Use of portable or mobile communications devices can degrade the performance of the equipment.

The LYRA x2 ventilator is in compliance with IEC 60601-1-2 for EMC.

The essential performance verified during the immunity testing based the below settings:

VCV mode, O2%: 21%, VT: 500 ml, Tinsp: 2.00 s, I:E: 1:2, f: 10 bpm, PEEP: 5 cmH2O.

Table E.1 Guidance and manufacturer's declaration-electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The ventilator 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.
RF emissions CISPR 11	Class A	The ventilator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Com plies	

Table E.2 Guidance and manufacturer's declaration-electromagnetic immunity[1]

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic Environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV 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 sup- ply lines ±1 kV for input/out-put lines (>3 m)	±2 kV for power sup- ply lines ±1 kV for input/out-put lines (>3 m)	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	±1 kV line(s) to line(s) ±2 kV (line(s) to earth	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	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in UT) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ventilator requires continued operation during power mains interruptions, it is recommended that the ventilator be powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	The power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61 000-4-6	3 Vrms 150 kHz to 80 MHz (for RGM, SpO2 performance) 3 Vrms 150 kHz to 80 MHz Outside ISM bandsa (for Ventilator	3 Vrms 3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the LYRA X2 ventilator, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. **Recommended separation distances** $d = 1.2\sqrt{P}$

	performance) 10 Vrms 150 kHz to 80 MHz In ISM bands[a] (for Ventilator performance)	10 Vrms	
Radiated RF IEC61000-4-3	3V/m 80MHz～2.5GHz (for RGM, SpO2 performance) 10V/m 80MHz～2.5GHz (for Ventilator performance)	3 V/m 10 V/m	$d = 1.2\sqrt{P}$ 80 MHz～800 MHz $d = 2.3\sqrt{P}$ 800 MHz～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). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [c], should be less than the compliance level in each frequency range [d]. Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

b. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c. 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 LYRA X2 ventilator is used exceeds the applicable RF compliance level above, the LYRA X2 ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the LYRA X2 ventilator.

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

Table E.3 Recommended separation distances between portable and mobile RF communications equipment and the ventilator

Rated maximum output power of transmitter(W)	Separation distance in meters (m) according to frequency of the transmitter		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 kHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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www.axcentmedical.com

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4000-000050-00 v1.00

axcent medical

MUSCA x2 | Transport Ventilator

User Manual

Contents

Contents....2
1 Equipment Description....10
1.1 Warning, Attention and tips....10
1.2 Overview....10
1.3 Safe Use of Oxygen....11
1.4 Ventilation/Operation....12
1.5 Patient Respiratory Hose Assembly....12
1.6 Software....13
1.7 Accessories/Spare Parts....13
1.8 Battery....13
1.9 Symbols that....14
2 Equipment Description....15
2.1 Purpose....15
2.2 Contraindications:....15
2.3 Scope of Application....15
2.4 User Qualification....16
2.5 The main composition of....16
2.6 Main Unit....16
2.7 Patient Respiratory Hose and Accessories....16
2.8 MUSCA x2 Main Unit instruction....17
3 Interface description....21
3.1 Composition of main interface....21
3.2 Main menu instruction....22
3.3 Alarm Message....26
3.4 Review Events....27
3.5 Setting of Alarm Limits....28
4 Installation....29
4.1 Overview....29
4.2 Boxed object....29
4.3 Install the battery....29
4.4 Connection of Oxygen Cylinder....29
4.5 Removal of Empty Cylinder....30
4.6 Connection of New Cylinder....30
4.7 Patient Respiratory Hose Assembly and Its Connection....30
4.8 Patient Breathing Valve....32
5 Ventilation Operation....33
5.1 Calibration of Touch Screen....33
5.2 Startup-Self-Checking....34
5.3 Select Ventilation Mode....35
5.4 Main Ventilation Parameters Setting....36
5.5 Details on Ventilation Modes....36
5.6 Execution of Ventilation....41
5.7 Monitoring of Respiration....42
5.8 CPR Ventilation....43
5.9 End Ventilation....45
5.10 Calculation of Storage Capacity/Operation....46
5.11 Alternative Breathing Apparatus....47
5.12 Battery Management....47
6 Sanitization....49
6.1 MUSCA x2 Main Unit....49

6.2 Respiratory Hose Assembly 49
6.3 Components and Accessories 49
6.4 Valve Fittings 49
6.5 Sanitization Methods 50
7 Functional Inspection 51
7.1 Inspection Cycle 51
7.2 Inspect System Air-Tightness 51
7.3 Examine Patient Breathing Valve 52
7.4 Machine Function Inspection 52
8 Trouble Shooting 54
8.1 Technical Failure 54
8.2 Physiological Alarm 54
8.3 System Alarm 55
9 Maintenance 56
9.1 Routine inspection 56
9.2 Battery 56
9.3 Accessories 57
9.4 Replace Filter 57
9.5 Storage 58
9.6 Disposal of Waste Equipment 58
10 MUSCA x2 Supplies Configuration 59
10.1 Standard Components 59
10.2 Optional Components 59
10.3 Ventilation Mode Configuration List 60
11 Technical Parameters 61
11.1 Medical Devices Management Category 61
11.2 Physical Specifications 61
11.3 Environmental specifications 61
11.4 Power Specifications 61
11.5 Ventilation mode 62
11.6 Supply specifications 62
11.7 Ventilator specifications 62
11.8 MUSCA x2 Product Structure Diagram 64
11.9 Available Minimum Oxygen Concentration 64
12 EMC 65
12.1 EMR Statement 65
12.2 EMI Statement - Requirements for All 65
12.3 Guide and Manufacturer Statement – EMI 67
12.4 Recommended isolation distance 68
12.5 Information on MUSCA x2 Patient's Physiological 69
12.6 Basic EMC Properties of MUSCA x2 transport 69
13 Warranty 71
14 Classification of Toxic/Harmful Substances 72
15 Storage and Transport 74

Product Information

Thank you for purchasing MUSCA x2 Transport Ventilator.

Before using the equipment, please read this manual carefully and understand the information contained in it so as to operate it properly. Keep this manual properly in any accessible place.

Product name：Emergency and Transport Ventilator
Model：MUSCA x2
Manufacturer：aXcent medical GmbH
Manufacturer address：Josef-Görres-Platz 2 56068 Koblenz / Germany
Revision date：2018-6

⚠ **Attention：**

This instrument is not intended for any family purpose.

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aXcent reserves the right to alter product specification without prior notice.

aXcent makes no warranty in any form concerning this manual, including (but not limited to) guarantee for implied marketability and adaptability for a specific purpose.

aXcent will, at its own discretion, take responsibility for safety, reliability and performance of the instrument in one of the following cases：

- any assembly, expansion, readjustment, improvement and repair operations are performed by any professional approved by aXcent;
- related electrical equipment is in compliance with national standards;
- the instrument is used in accordance with the operation instructions.

aXcent will be responsible for safety, reliability and operation condition of the product in one of the following cases：

- any component is dismantled, expanded or re-adjusted;
- the instrument is repaired or changed not by any personnel approved by aXcent;
- the product is not used correctly in compliance with this Operating Manual.

Maintenance Service

Scope of Charge-Free Service：

- Charge-free service is provided for any equipment in the range of aXcent's warranty terms.

Scope of Paid Service：

- Paid service is provided for any equipment beyond the range of aXcent's warranty terms.

As well as in one of the following cases even during the warranty period:

- Damage caused by personal fault;
- Improper use;
- Grid voltage beyond the limits;
- Irresistible natural disaster;
- Use of spare part/ consumables not approved or machine service performed by personal not authorized by aXcent.

Warning：

Failure to implement a set of satisfactory service/maintenance plan by any hospital or institute responsible for using this instrument may cause malfunction of it or even endanger body health.

Warranty

Manufacturing Process and Raw Material：

aXcent warrants that no failure will be resulted from any defect in manufacturing process or raw material when this instrument is used and serviced correctly.

After-Sales Service Unit

aXcent medical GmbH

After-Sales Service Dept.,

Josef-Görres-Platz 2

56068 Koblenz / Germany

Return

Return Procedure

Any return as necessary shall comply with the following procedure:

- Acquire right of return: Contact aXcent's customer service, and provide the product ID labeled on external packaging of the instrument, which must be legible for return approval. Indicate product model and describe the reason for return.
- Freight: Any expenses (including customs fee) incurred in transporting the instrument to aXcent shall be paid by the user.

Important Information

1. After purchase of the product, the customer shall take full responsibility for maintenance and management of it.
2. Quality assurance will not cover the following even during the warranty period：

- any damage or loss resulted from improper use or misuse of the product;
- any damage or loss caused by force majeure such as fire, earthquake, flood or lightning;
- any damage or loss attributed to failure to meet any operating condition required for the system, such as insufficient power supply, improper installation or unfavorable environmental conditions;
- any damage or loss incurred due to use of the system in the region not initially intended for it; and
- any damage or loss caused due to purchase from any unauthorized dealer or agent.

3. This equipment can be used only by certified medical staff.
4. Any software or hardware of this product must not be changed or modified without authorization.
5. In any case aXcent will take no responsibility for problem, damage or loss resulted from re-installation, change or repair of the system performed not by personnel authorized by aXcent.
6. This system is intended to provide the data required for clinical diagnosis for physicians. The physician takes responsibility for diagnosis process. aXcent takes no responsibility for any diagnosis process.
7. Be sure to back any key data to external storage medium, such as clinography and notes.
8. aXcent takes no liability for loss of data stored in the system due to the operator's fault or any exceptional condition.
9. This manual contains warnings for foreseeable potential hazards. User shall keep watch at any time for any hazard not stated in the manual. aXcent takes no responsibility for damage or loss resulted from negligence or failure to observe the preventive measures stated in this manual.
10. This manual must be handed over to the successor when the system administrator is

changed.

1 Equipment Description

Please read these safety instructions carefully. These safety instructions are an integral part of the equipment and must be kept accessible for review whenever necessary. For purpose of safety, the following information must be paid attention to.

1.1 Warning, Attention and tips

The following safety marks are used in this manual:

Warning:

Indicating any risk of harm to patient and/or user.

Attention:

Indicating potential equipment damage and undesired treatment effect.

Tip:

Giving useful indicative information.

1.2 Overview

- A functional inspection must be performed before use of the equipment (refer to Section 7 - Functional Inspection).
- Please observe the instructions in Section 6 - Sanitization to prevent infection or bacillosis.

Warning:

- 【After the training】You can operate MUSCA x2 only after you have been provided with proper medical training in and technical guidance on respiration equipment. Improper use of it may cause serious injury to body.
- 【Do not leave MUSCA x2 in ventilation】 Do not leave a patient or respirator in ventilation to respond in time to any transport (such as patient's worsening state of an illness or machine fault) to minimize the patient's injury.
- MUSCA x2 can be used for the intended purpose (refer to Section 2.1 - Purpose for more details).
- 【Hyperbaric chamber】Do not use MUSCA x2 in hyperbaric application (hyperbaric chamber).
- 【Danger】 Do not use MUSCA x2 in any explosive or toxic environment.
- 【Fire】 Do not use MUSCA x2 in any oxygen-rich or inflammable environment.

- 【Maintenance personnel qualification】This equipment can be repaired and maintained only by aXcent or any professionals authorized by it.
- 【Please do not open】 Only maintenance personnel can open the cover, replace or modify spare parts outside and inside MUSCA x2.

Caution：

- 【Other equipment】Any device or equipment emitting high-frequency radiation (e.g. cell phone, radio) must be kept a minimum distance of 1 meter from MUSCA x2 to prevent any malfunction in it.
- 【The power converter】 When the respirator is powered by any external power supply, the power supply shall be connected to a pluggable interface so that it can be disconnected quickly in case of failure.
- 【External power supply】 When the respirator is powered by an external power supply, please ensure that the power line shall not hinder. If not necessary (when battery capacity is lower than 20% or MUSCA x2 is used in an uninterrupted way for a long time), please do not use any external power supply; instead, please give priority to power MUSCA x2 by internal battery.
- 【The standby】An alternative secondary respiration device must be provided in case of failure of the primary equipment.
- 【Replace Filter】After the equipment is used in any dusty environment, replace the filter in accordance with Section 9.4 - Replace Filter.
- 【Liquid】 Please do not immerse MUSCA x2 in any liquid. If liquid penetrates into cover, it shall lead to damage of equipment.

1.3 Safe Use of Oxygen

Warning：

- High-pressure oxygen and combustible (lubricating grease, engine oil, alcohol, etc.) may give rise to an explosion when they meet each other.
- Supply of oxygen in high concentration to a patient for a long time may generate toxic effect. Patients differ in bearing duration due to age, physical condition, etc. So please adopt proper way of ventilation according to a patient's condition.
- Keep equipment and all joints clean and free from any engine oil or lubricating grease.
- Before operating oxygen supply device, please wear a clean pair of medical gloves.
- No open flame nearby equipment and related supporting facilities

Caution:

- While installing and replacing an oxygen cylinder, please manually screw down knob switches on the oxygen cylinder and reducing valve. Do not use any tool to prevent overexerting yourself from damaging thread and sealing materials and leading to leakage.
- Please take measures to prevent an oxygen cylinder from toppling and falling. A toppling and falling oxygen cylinder may damage reducing valve or oxygen valve and even lead to an explosion in serious condition.
- Slowly open oxygen cylinder valve because it may give rise to sharp rise of pressure to impact valve parts and result in their damage by opening oxygen cylinder valve too intensely and quickly.
- Do not completely use up oxygen in the oxygen cylinder to prevent humid air in surrounding environment from flowing into the oxygen cylinder to corrode the oxygen cylinder.

1.4 Ventilation/Operation

- During ventilation, uninterrupted observation of both the patient and respiratory equipment must be performed.
- Prolonged breathing through respirator may result in atrophy of patient's respiratory muscles.
- Lengthy ventilation may cause patient's respiratory tract dry. Make sure sufficient natural air is available for adjustment of respiration.
- Make high-pressure ventilation in a short time under instruction of an physician. Because uninterrupted high-pressure ventilation for a long time may injure a patient. Guarantee unimpeded respiratory hose of patient to prevent influencing ventilation function of equipment.

1.5 Patient Respiratory Hose Assembly

Warning:

- Those using patient's respiratory hose assembly must have taken professional medical training and technical instruction on respiratory equipment for improper use may lead to serious physical injury.
- Please refer to related contents in the manual and make functional test and visual inspection before using respiratory hose assembly.

- Before connecting to patient, please check whether direction of oxygen flow transported to patient is correct and whether the respiratory hose is unimpeded.
- Patient respiratory hose assembly can be used only for the intended purpose.
- Patient respiratory hose assembly is unsuitable for high pressure applications (hyperbaric chamber).

1.6 Software

Many quality assurance measures have been taken in development of equipment software to minimize the risks potentially caused by software defect.

1.7 Accessories/Spare Parts

⚠ **Caution:**

- 【To prevent the sun】Proper measures shall be taken to prevent prolonged exposure of any rubber parts to UV or direct sun and brittleness caused thereby.
- 【Use approved accessories only】 Use of accessories of other manufacturers may give rise to fault due to incompatibility. **Please bear in mind that warranty rights and liabilities shall be invalidated in such cases:** do not use accessories recommended in the manual or original spare parts.

1.8 Battery

⚠ **Warning:**

【Low battery】 When MUSCA x2 alarms in low battery, please make any of the following operations:

- Replace battery by fully charged battery.
- Connect MUSCA x2 with external MUSCA x2 power supply.

⚠ **Attention:**

[Keep battery installation] In order to enable MUSCA x2 to make sustainable operation, it is advised to always install fully charged battery (even though when MUSCA x2 is powered by external power supply).

1.9 Symbols

Description ICONS and symbols

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Refer to the document attached for more details		Refer to the operating instructions for more details
	Date of production		BF type applications
	Class-II equipment	IPX4	Waterproof level
	Do not reject into dustbin		Non-ionizing radiation
	Refer to the document attached/manual		Main Unit Switch
	Power supply by adapter		Power supply by battery
	menu		Alarm mute
	Lock/unlock		Manual ventilation
	Air inlet		PEEP control
100%	Battery level indication		Adapter off
20	The product contains some hazardous substance. Use it at ease in the eco-friendly service life but put it in the recovery cycle system after it is beyond the eco-friendly service life which is 20 years.		

2 Equipment Description

2.1 Purpose

MUSCA x2 is an automatic oxygen equipment, suitable for transport and transportation while tidal volume is more than 50ml. It supports noninvasive and invasive ventilation.

MUSCA x2 can be operated only when securely fixed to or mounted on approved conveying platform.

2.2 Contraindications:

Bullae of lung, pneumothorax, hemoptysis, active tuberculosis, bronchopleural fistula, pleural effusion, acute myocardial infarction.

⚠ **Warning:**

MUSCA x2 is suitable for patient's tidal volume more than 50ml, offering A/C, invasive and noninvasive ventilation support.

2.3 Scope of Application

MUSCA x2 can be applied in the following cases:

Emergencies

- First-aid resuscitation on the site;
- Ongoing transport lasting for a long time (e.g. fire); and
- Temporary oxygen uptake via respiratory mask and ventilation via tracheal cannula.

Transfer of patient

- During first-aid treatment on surface, on the sea or in the air;
- During transfer from ward to treatment room in hospital;
- During transfer from hospital to any other location.
- Use in other situations according to medical advice of physician.

Temporary ventilation in hospital

- Recovery room;
- ICU;
- Preparation for operation and the stage subsequent thereto;
- transport room.

2.4 User Qualification

The person operating MUSCA x2 must be qualified and meet the following conditions:

- Provided with proper medical training in and technical guidance on respiration equipment.
- Provided with training in clinical application with MUSCA x2 by aXcent medical.
- Improper operation of the equipment may cause serious injury to persons (the operator and patient).

2.5 The main composition of

MUSCA x2 transport Ventilator The main composition of

consists of a main unit, respiratory valve, and rechargeable lithium battery.

All components necessary for MUSCA x2 operating as a ventilation system have been designed by aXcent.

2.6 Main Unit

MUSCA x2 can be used for treatment of breathlessness and to provide breathing support. By means of adjustable respiration parameter, you can keep ventilation through the respirator consistent with patient's own breath.

- This unit provides two ventilation control modes, pressure control and volume control.
- Inspiration triggering mode for this unit is pressure activation.
- This equipment provides electronic PEEP function.
- This unit allows nine respiration modes (IPPV/V-AC/V-SIMV/P-AC/P-SIMV/PCV/CPAP/CPR/Manual) which can be selected to meet patient's breathing in various states.
- This equipment can make adjustment to oxygen concentration.
- The large 7" screen provided for the equipment displays patient's breathing parameters and pressure curve,
- The screen is furnished with touch control function.

2.7 Patient Respiratory Hose and Accessories

The inhaled air is conveyed to the patient through patient respiratory hose assembly, including respiratory hose and patient respiratory valve.

- **Two optional types of respiratory hoses are available:**

1. Reusable respiratory hose.
2. Disposable respiratory hose.

- **Patient breathing valve:**

furnished with power-controlled PEEP valve structure for high-precision control of positive end-expiratory pressure (PEEP) and continuous positive airway pressure (CPAP).

2.8 MUSCA x2 Main Unit instruction

2.8.1 Main Unit-Front View

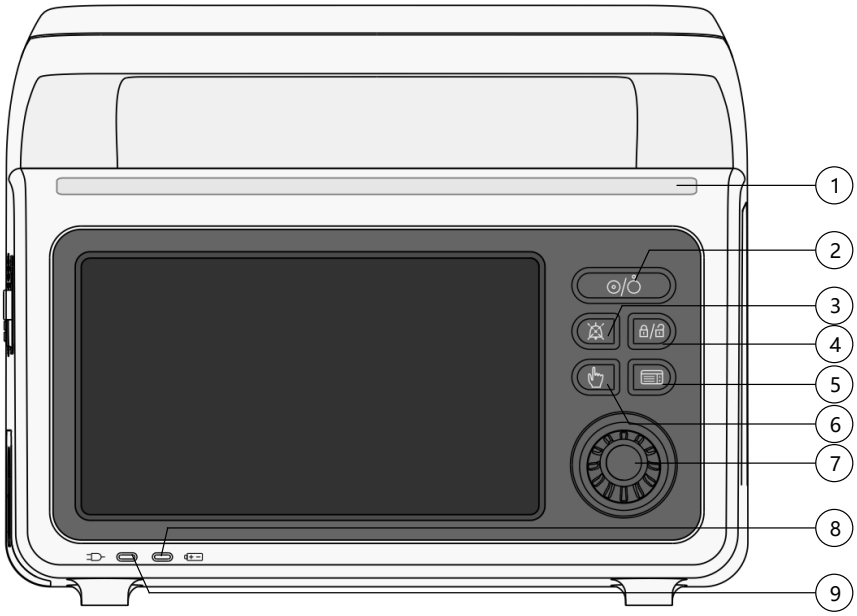


FIGURE 1 Main Unit (Front View)

PARTS	DESCRIPTION
1 warning LED	When it alarms, it displays red and yellow flicker, signaling different alarm priority levels. Red=top priority, yellow=intermediate priority, off=no alarm.
2 Start/Shut Down button	Press it to start. , Long press it for 3 seconds to shut down the equipment.
3 Acoustic alarm mute button	Press it to keep acoustic alarm mute for a certain period (up to 120 seconds). When the alarm stays mute, the indicator LED next to it will be turned on, but any visual

	alarm (e.g. warning LED, status bar) will not be disabled.
4 Screen locking button	It is used for locking touch screen. When touch screen is enabled, press the button and the touch screen will be disabled; otherwise, press the button and the touch screen will be enabled.
5 Main menu button	Press it to access main menu, which contains time, system, calibration and record settings and system information.
6 Manual ventilation button	Press it to manually control ventilation **control** mode.
7 Navigation knob	Used to access various operation interfaces as shown below: Turn the knob to forward and backward move the focus; press the button to enter the page selected or select the selected label or save settings; while setting parameters, forward turn to add selected parameters to be set and backward turn to decrease selected parameters to be set.
8 Battery indicator	In charging, its indicator will flicker; when it is fully charged or its battery is being used, its indicator will be normally on. Tips: It indicates whether the respirator depends on internal battery or external power supply in operation.
9 Indicator of external power supply	The indicator will be normally on when MUSCA x2 connects to power adapter. Tips: When the respirator is switched from external power supply to internal power supply, the respirator is still normally working.

2.8.2 Main Unit-Rear View

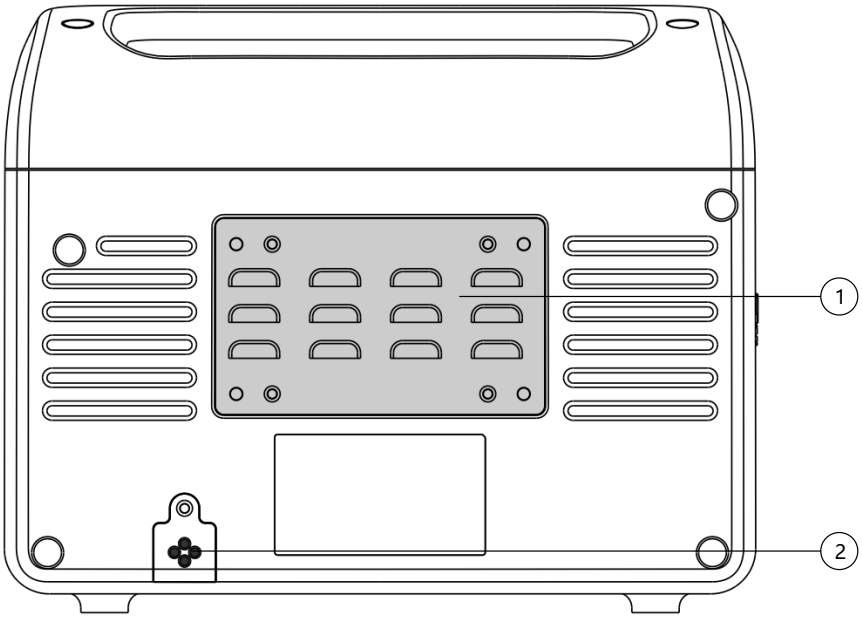


FIGURE 2 Main Unit (Rear View)

PARTS	DESCRIPTION
1 Radiating panel	It is used for radiating host, which must not be blocked.
2 air inlet	Air inlet and safety valve outlet, which shall not be blocked.

2.8.3 Main Unit-Left View

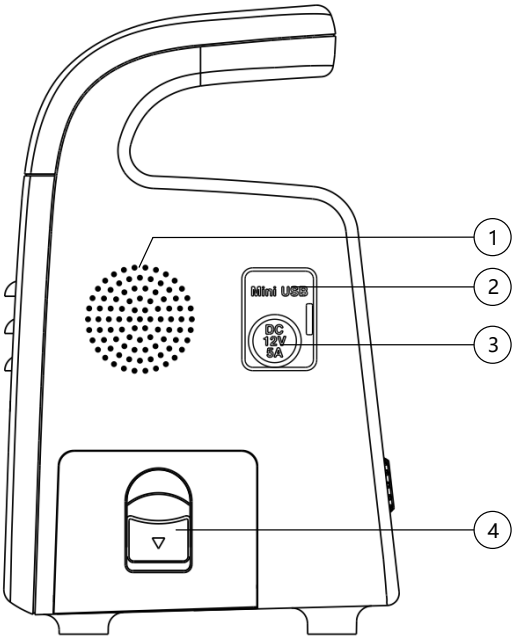


FIGURE 3 Main Unit (Left View)

PARTS	DESCRIPTION
1 speaker	For acoustic indication or alarm.
2 USB port	Covered with a rubber cap, and used for software maintenance and upgrade.
3 DC port	Covered with a rubber cap, and used for connection of power adapter.
4 battery cartridge	For mounting of battery.

2.8.4 Wain Unit-Right View

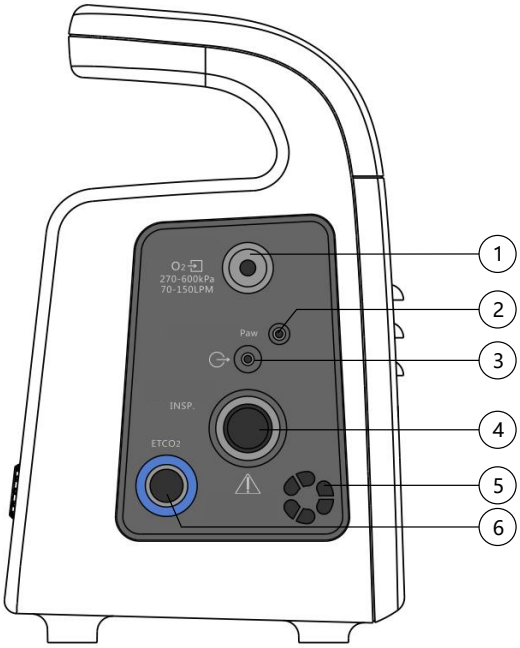


FIGURE 4 Main Unit（Right View）

PARTS	DESCRIPTION
1 O2 source interface	For connection to O2 source.
2 pressure measurement port	Used for measurement of airway pressure or DC power supply on aXcent e or helicopter.
3 PEEP air supply port	For connection of white hose in respiration hose loop.
4 fresh air outlet	For connection of respiration hose to patient.
5 air inlet	For inhalation of transport air.
6 ETCO2 port	Connect CO2

3 Interface description

3.1 Composition of main interface

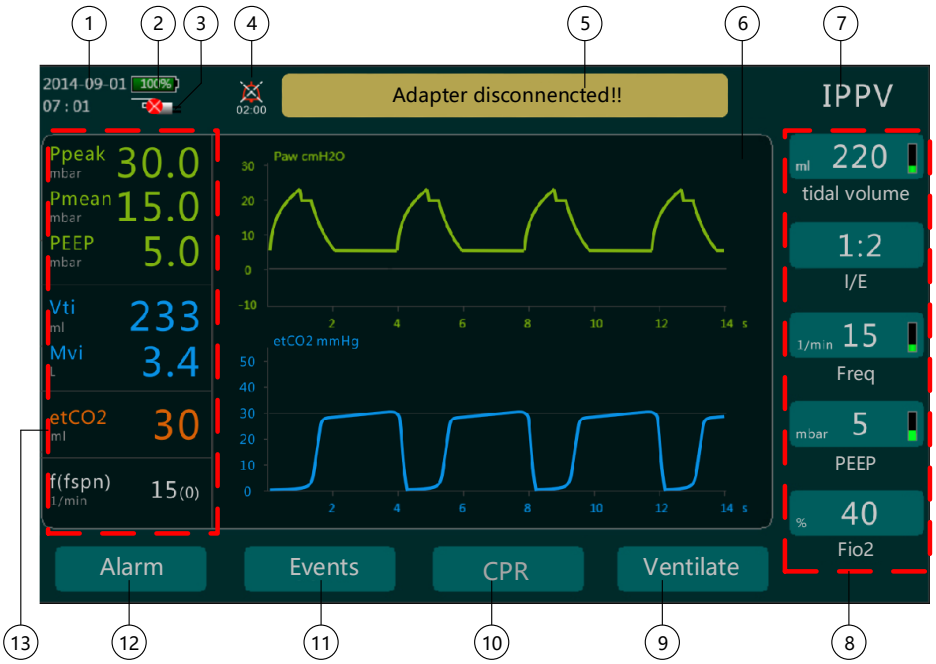


FIGURE 5 Main interface

PARTS	DESCRIPTION
1 Time/date	For real-time display of current time and date.
2 Battery state	battery level or recharging state.
3 Adapter state	For real-time indication of current power adapter status
4 Alarm mute icon	For real-time indication of alarm mute status.
5 Warning message indication	Real-time indication of warning message.
6 Waveform	Real-time display of current respiration parameter in the form of waveform.
7 Ventilation mode	For indication of current user ventilation mode and re-selection of mode from a drop list.
8 Main ventilation parameter setting	When selected, you can change parameter value for current mode by using the navigation knob.
9 Ventilate	Use it to access Ventilate.
10 CPR	For real-time display of current CPR function status.

11 Logs	Use it to access system logs.
12 Alarm limits	Use it to access alarm limits.
13 Real-time parameter monitoring	For monitoring of real-time measurement of respiration parameters on the ventilator.

Caution:

Any operation which is accessible with touch screen is also accessible with the navigation knob.

3.2 Main menu instruction

In the main menu, you may optimize host settings to adapt to different service conditions. Call out main menu by machinery button of <Main menu> and call out required setting interface by navigation knob or touch:

FIGURE 6 Menu

PARTS	DESCRIPTION
1 Ventilate	Set ventilation in current mode.
2 Alarm	Set alarm volume and way.
3 System	Set screen brightness, unit, desktop style, waveform style, voice, and ETCO2.
4 Time	Set system time of equipment
5 Calibration	Calibrate equipment's air proportion valve, oxygen proportion valve and PEEP proportion valve.

6 About Host	View the equipment's main software version No. and control software version No.

3.2.1 Full Ventilation Parameters Setting

You can set ventilation control parameters based on patient's respiratory physiological characteristics (as shown below).

The setting procedure is given below:

1. Select Ventilation button by using the navigation knob to pop up ventilation setting window.
2. Select the ventilation parameter value to be changed by pressing navigation knob or directly clicking on it.
3. Modify the selected ventilation parameter value and press navigation knob again to confirm the modification.
4. Repeat Steps 2 and 3 to modify other parameter limits.
5. Exit from the main menu by clicking on "X" button or pressing Main Menu button again, Cancel parameter modification.

FIGURE 7 Ventilate

3.2.2 Setting Alarm Volume

In the main menu interface, select < Alarm > soft button and enter the alarm setting interface(As shown below).

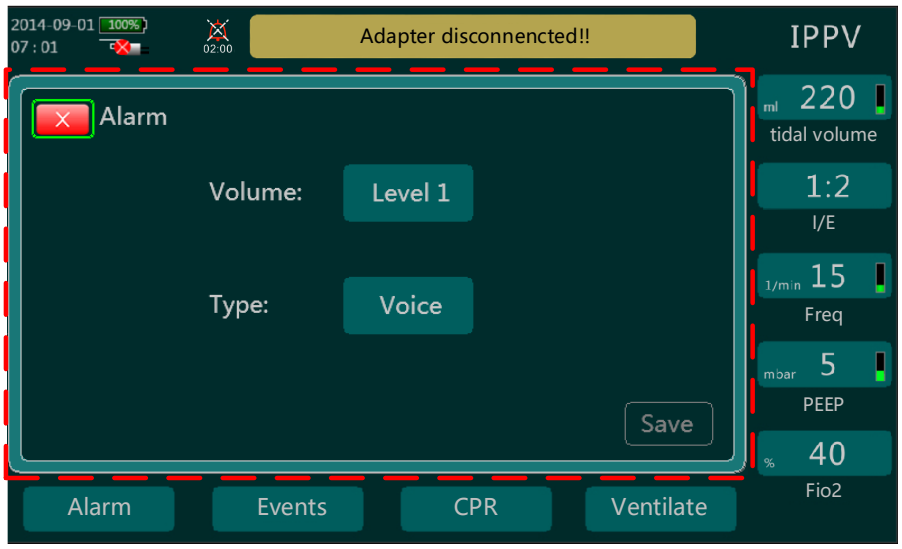


FIGURE 8 Alarm

PARTS	DESCRIPTION
1 Volume	By default three levels are available. The available options are: shut down, Level 1, Level 2, and Level 3.
2 Type	The default mode is voice alarm. The available options are buzzer and voice alarm.

3.2.3 System Settings

In the main menu interface, select < System setting > soft button to enter the system setting interface (as shown below).

FIGURE 9 System

PARTS	DESCRIPTION
1 Luminance	By default two levels are available. The available options are: Level 1, Level 2, and Level 3.
2 Pressure unit	The default unit is mbar. The available options are mbar, hPa, and cmH2O.
3 Desktop style	The default style is Dark Green. The available options are Dark Green, Dark Blue and Gray White.
4 Waveform style	The default style is Filling. The available options are Filling and Solid Line.
5 Language	The default language is Chinese. The available options are Chinese and English, Turkish.
6 EtCO2	Open or close.

3.2.4 Time setting

In the main menu interface, select < Time > soft button to enter the time interface (as shown below).

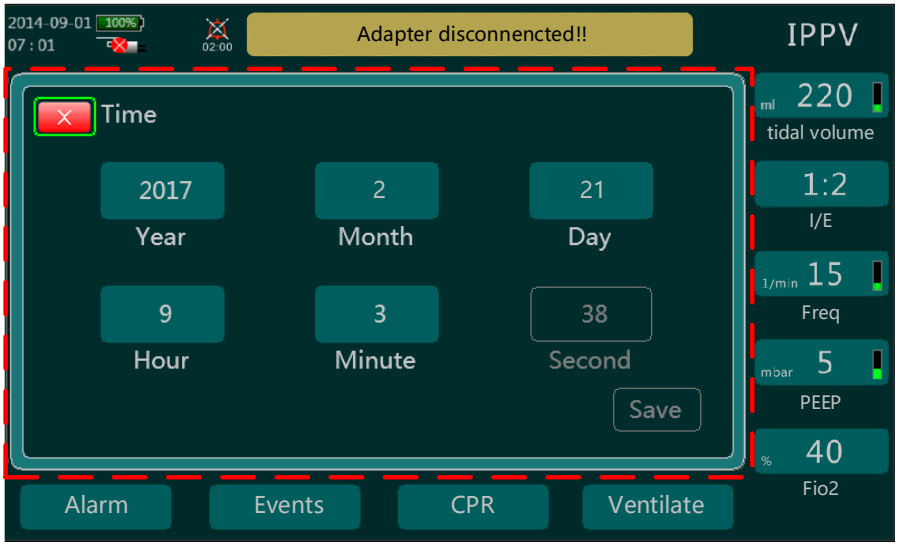


FIGURE 10 Time

3.2.5 Calibration

In the main menu interface, select <Calibration> soft button to enter calibration interface to calibrate air proportion valve, oxygen proportion valve and PEEP proportion valve (as shown in the following figure).

FIGURE 11 Calibration

3.2.6 About Host

In the main menu interface, select <About host> soft button to view software version (as shown in the following figure).

FIGURE 12 About Host

3.3 Alarm Message

Press the alarm tips button in the main interface and it will display alarm information in the top priority. If there are many alarms,

You can access alarm message by pressing alarm indication button in main interface (as shown below).

FIGURE 13 Alarm Table

3.4 Review Events

You can review system logs by clicking on Events button in main interface (as shown below).

FIGURE 14 Events

Up to 50 items of log message can be stored in the system. The older Events will be overwritten by the newer ones. In reviewing logs, pay attention to the following:

- Events message structure: time + type + content of message.
- Events time: the time of recording the Events.
- Events type: alarm message, user access message, and system operation message. (for the time being only alarm message is available)

- Events message: specific message description.
- Events color: red - high priority; yellow - medium priority; black - low priority.

3.5 Setting of Alarm Limits

In the main menu interface, select < Alarm Limits > soft button to enter the Alarm Limits interface, you can set alarm limits based on patient's respiratory physiological characteristics (as shown below).

FIGURE 15 Alarm

PARTS	PARTS
1 Upper airway pressure limit	**6 Suffocation duration**
2 Lower airway pressure limit	**7 Upper tidal volume limit**
3 Upper ventilation rate (per min.) limit	**8 Lower tidal volume limit**
4 Lower ventilation rate (per min.) limit	**9 Upper EtCO2 limit**
5 Upper respiration frequency limit	**10 Lower EtCO2 limit**

4 Installation

4.1 Overview

Generally, MUSCA x2 needs to be mounted only fixed onto an aXcent helicopter or aircraft. In such case, we will supply a specific mounting bracket as an accessory.

If MUSCA x2 is supplied by being fixed completely onto a stretcher or packed in a first-aid package as an assembly, this equipment is well ready for use without mounting.

Warning:

After mounting, you must perform a functional inspection (refer to Section 7 - Functional Inspection) to ensure proper operation of the equipment.

4.2 Boxed object

MUSCA x2 transport Ventilator is packaged in a single case. For details on packing list, refer to "10. MUSCA x2 Supplies Configuration".

4.3 Install the battery

MUSCA x2 is equipped with chargeable lithium battery which is installed as shown in the following figure.

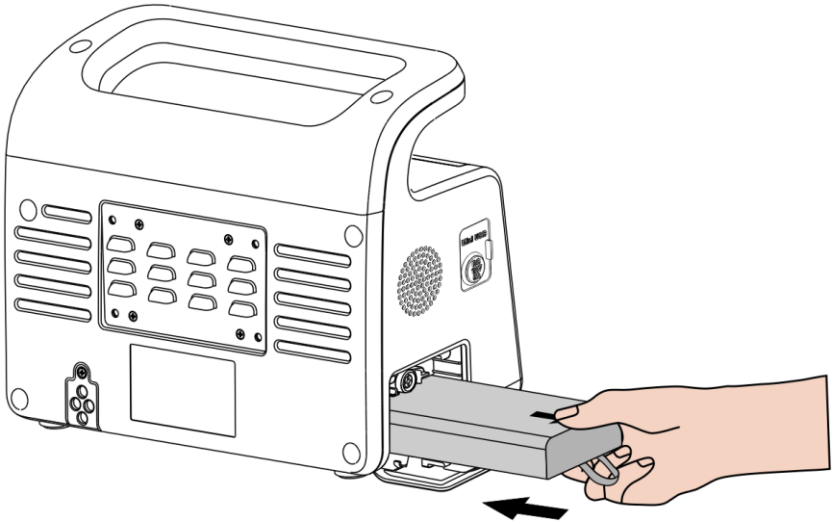


FIGURE 16 Install the battery

4.4 Connection of Oxygen Cylinder

Warning:

- Before operating oxygen supply device, please wear a clean pair of medical gloves. Hydrocarbon (such as engine oil, lubricating grease, alcohol, hand cream, or adhesive plaster) may lead to an explosion by contacting high-pressure oxygen.
- Do not use wrench or any tool to tighten or loosen any connecting nut.

4.5 Removal of Empty Cylinder

1. 1. Shut off the air valve of the cylinder.

- Start MUSCA x2 by using the Start-Shut Down button, so as to release any residual oxygen and relieve any pressure inside the equipment.
- Release the switching valve by hand only when the reading on reducing valve is 0 bar.

2. Shut down MUSCA x2.
3. Loosen the connecting nut on the cylinder by hand.

4.6 Connection of New Cylinder

1. Open the valve on new cylinder for a short moment and then shut it off, so as to remove any potential dirt at the outlet.

Warning:

- When connecting gas supply equipment, make sure the patient is not connected to MUSCA x2. Or otherwise automatic self-detection feature of the equipment may start and cause negative effect.
- Keep the valve port from body to avoid potential personal injury!

2. Connect reducing valve to port of the cylinder. Tighten the nut by hand.
3. Screw the pressure hose with 9/16-18UNF connecting nut into the outlet of reducing valve.
4. Connect the other end of the pressure hose to the air source port on MUSCA x2.

4.7 Patient Respiratory Hose Assembly and Its Connection

MUSCA x2 provides a reusable or disposable respiration management assembly. The assembly will be connected to the respirator and related accessories in accordance with the following procedure (as shown below).

1. Connect respiratory hose, patient valve in the respiratory hose assembly in accordance with the following method.
2. Connect the rubber hose of patient value to pressure monitoring port on the main unit.
3. Connect the PU hose of patient valve to PEEP port on the main unit.
4. Connect breathing hose to the fresh gas intake. Be sure not to bend any connected air hose.
5. For connection between any other accessories and to the patient, refer the following Hose Accessories Connection Diagram.
6. In optional configuration of ETCO2 module, connect one end of mainstream CO2 module to patient and the other end to respiratory valve of patient and connect ETCO2 data acquisition line to ETCO2 sampling port.

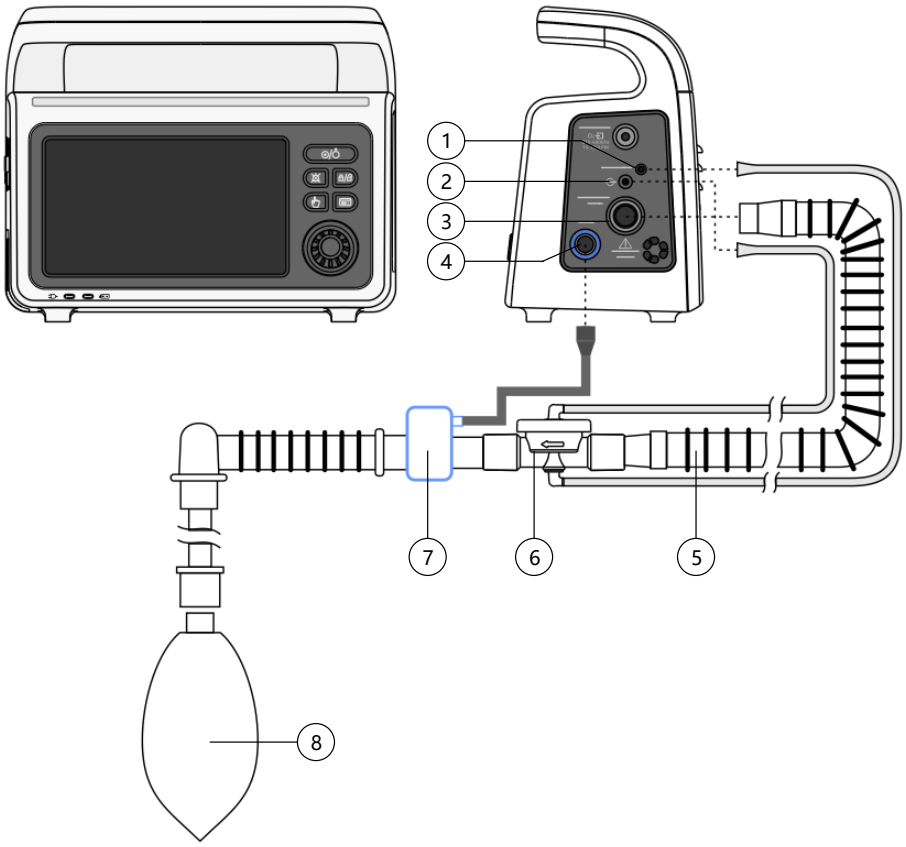


FIGURE 17 Accessories Connection Diagram

PARTS	PARTS
1 pressure measuring port	**5 Hose**
2 PEEP Port	**6 patient Valve**
3 fresh gas intake (to patient)	**7 Mainstream CO2 module (used in optional configuration)**
4 ETCO2 port	**8 simulative lung (patient)**

Warning:

Handle breathing hose, PU hose and rubber hose by holding ends of them to prevent any damage to or break of them.

Any disposal hose assembly shall be disposed after being used.

4.8 Patient Breathing Valve

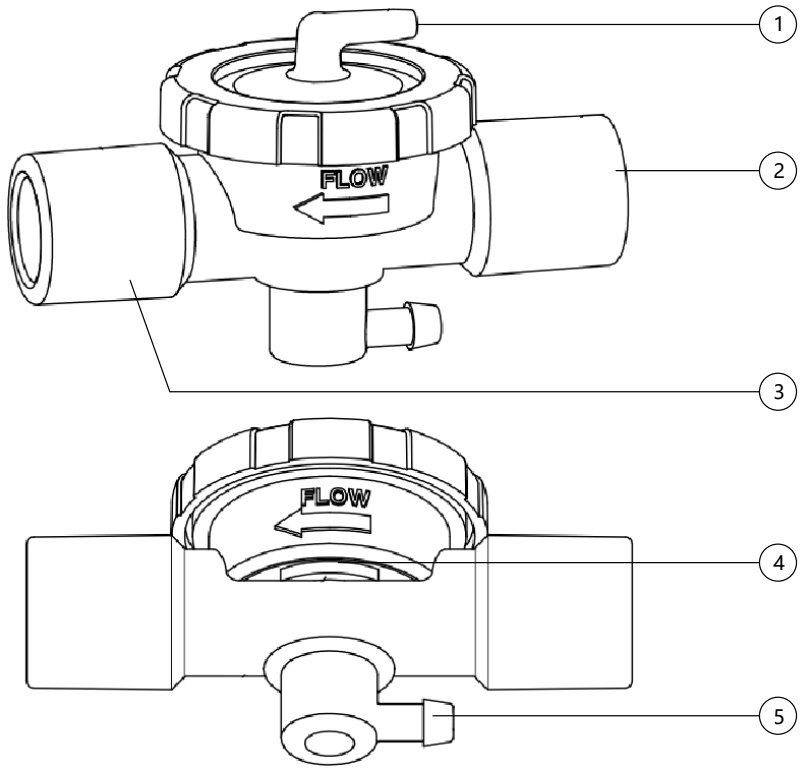


FIGURE 18 Patient Breathing Valve

PARTS	DESCRIPTION
1 PEEP air source port (self-reliant unit)	Connect to PEEP air supply port on main unit.
2 Air inlet (self-reliant unit)	Connect to fresh air inlet of main unit.
3 Patient connection port (for connection of mask/ cannula)	Connect to the patient.
4 Air outlet	Patient's expired air outlet, which shall not be blocked.
5 Airway pressure measuring port	Connect to pressure measuring port on main unit.

Warning:

The manufacturer aXcent medical GmbH shall not be liable for any product performance problem resulting from use of respiratory hose assembly provided by any other manufacturer.

5 Ventilation Operation

5.1 Calibration of Touch Screen

For the initial operation, the system will automatically enter touch screen calibration. User can click the touch points to finish calibration of the first (at the lower left corner) and the second (at the upper right corner) points, and then click a third point at any position of the screen to complete the calibration procedure (as shown below).

FIGURE 19 Click on the bottom left corner

FIGURE 20 Click on the top right corner

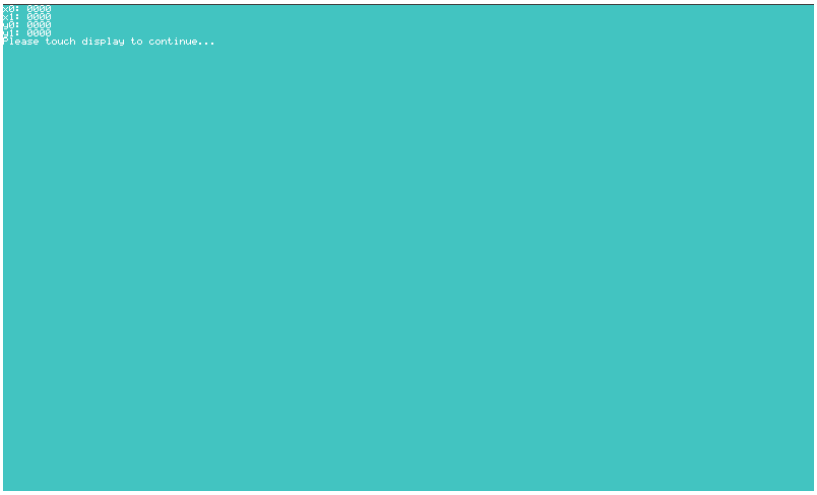


FIGURE 21 Click on any location

5.2 Startup-Self-Checking

1. Slowly open the switching valve on the oxygen cylinder. Current pressure of the cylinder can be read out on the pressure meter of the reducing valve.
2. Calculate the ventilation duration which the current storage volume can maintain (refer to Calculation of Oxygen Storage/Ventilation Duration). You need to replace the oxygen cylinder at a proper time to ensure the respirator can operate for a period of sufficient length, for example, when pressure of the cylinder is lower than 50 bar.
3. Press down Start/Shut Down button to start MUSCA x2. At this moment a progress bar indication self-checking is displayed on the screen. Upon end of the bar, the main interface appears, and voice prompts are given by the system, such as "open oxygen cylinder", "select respiration mode" and "adjust settings".
4. If self-checking fails, the following frame will be displayed on the screen. At this moment the respirator is unavailable.

FIGURE 22 Startup-Self-Checking

FIGURE 23 Error code

5. It indicates that the main unit operates normally when no error message is displayed on the main interface. At this moment the respirator will not execute any ventilation mode or parameter, but pop up a Select transport Ventilation Mode dialog for your selection.

- You can directly confirm the dialog and respirator will execute the default ventilation

mode and parameters.

- Alternatively you can click on Ventilation Mode and select the desired mode from the drop down list, and then set the related parameters in the pop-up parameter setting window and save it, and respirator will execute your selection.

A detailed description of the aforesaid operations is given in the following section.

6. After setting respiration parameters and ventilation mode, make connection to the patient.
7. During ventilation, adjust respiration parameters as necessary for the patient.

Caution：

Self-checking should not be a substitute for functional inspection. Before using the equipment, functional inspection shall be performed in accordance with Section 7 - Functional Inspection.

5.3 Select Ventilation Mode

To select ventilation mode, click on Ventilation Mode and select the desired mode from the drop down list (as shown below).

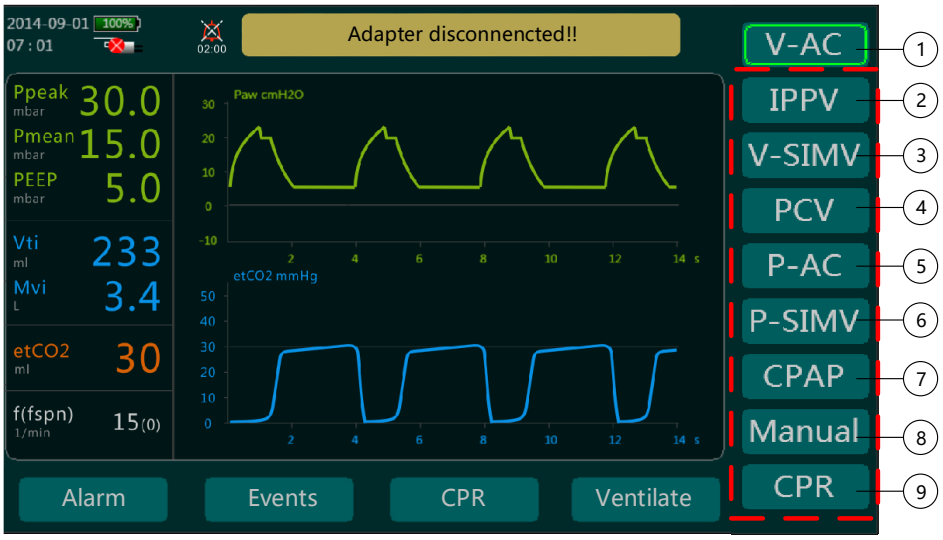


FIGURE 24 Ventilation Mode

PARTS	PARTS
1 V-AC Mode	**6 P-SIMV Mode**
2 IPPV Mode	**7 CPAP Mode**
3 V-SIMV Mode	**8 Manual Mode**
4 PVC Mode	**9 CPR Mode**
5 P-AC Mode	

5.4 Main Ventilation Parameters Setting

For convenience of operation and review, 5 major ventilation parameters are provided at the right side of the main interface (as shown below).

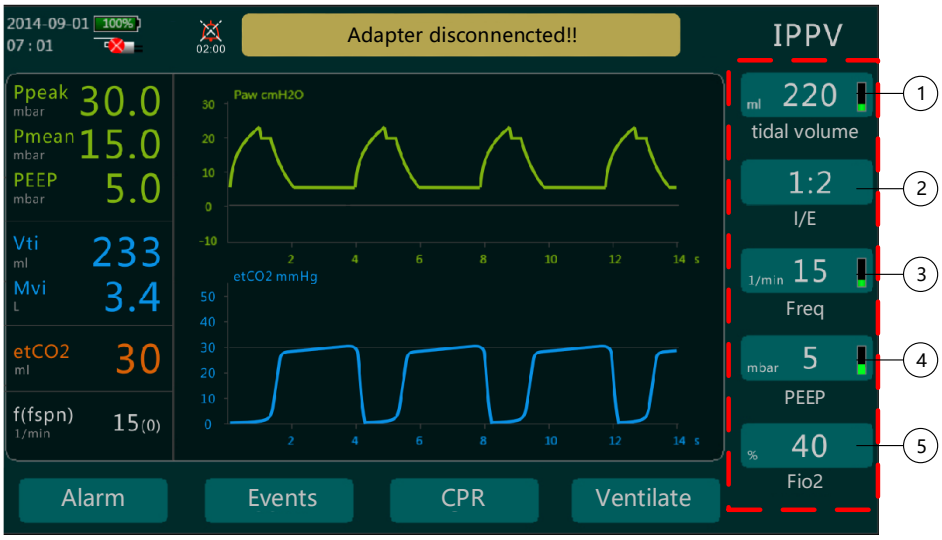


FIGURE 25 Main Ventilation Parameters

PARTS	PARTS
1 Inspiratory pressure (tidal volume in case of volume control mode)	
2 Inhalation/expiration ratio (I/E)	**4 PEEP (or CPAP)**
3 Respiration frequency	**5 Oxygen concentration**

5.5 Details on Ventilation Modes

MUSCA x2 allows different ventilation modes based on patient's condition.

5.5.1 IPPV and PVC

- **IPPV**

In case of mechanical ventilation in IPPV (Intermittent Positive Pressure Ventilation), the respirator always offers positive pressure ventilation, supplying rising pressure during inspiration and baseline pressure during expiration. In other word, consecutive respiration support is provided for breathless patient and each respiration is mandatory. MUSCA x2 operates in volume-controlled IPPV, where air in preset tidal volume is conveyed to the patient at a constant flow rate and preset respiration frequency and for the preset respiration duration, so that the patient will obtain stable tidal volume in variable pressure, with inspiration peak pressure kept high in case of poor compliance or high air duct resistance and low in case of good conformity or low airway resistance. The tidal volume, I/E and inspired air flow rate for the patient are completely controlled by respirator, which supplies constant inspired air flow rate and all respiratory power.

IPPV, also known as Controlled Mechanical Ventilation (CMV), is a ventilation technology commonly used in clinic applications and mainly for patients without spontaneous breathing. The respirator will provide patient with positive pressure ventilation based on the preset ventilation parameters regardless of the patient's own breathing condition.

A typical pressure waveform of IPPV is shown below：

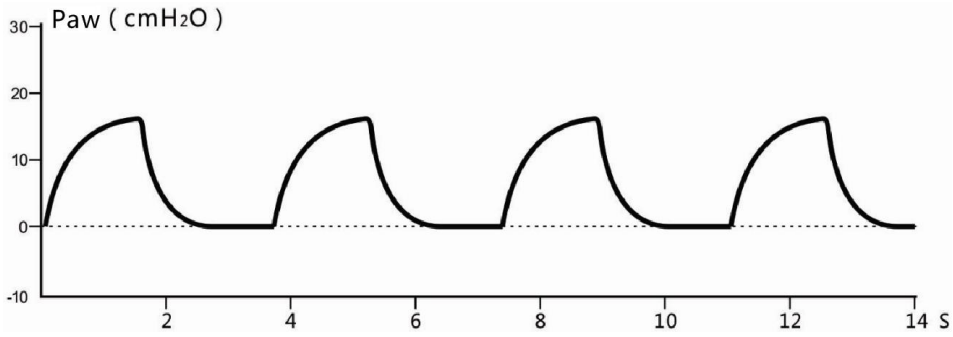


FIGURE 26 IPPV

- **PCV**

In PCV (Pressure Controlled Ventilation), airway pressure and inspiration duration are preset. After inspiration is started, air flow rate is raised quickly to the preset pressure level and then slowed down by the feedback system and maintained at the preset pressure till end of inspiration, and then expiration is started. Each ventilation is of full load based on preset pressure. In PCV, airway pressure falls, and there is no peak pressure, and rare barotrauma, which is beneficial for aeration of pulmonary alveolus, improvement to ventilation-blood stream rate and optimization of air exchange. PCV is primarily used for newborn, infants and patients suffering respiratory insufficiency, severe unbalancing ventilation-blood stream rate resulted from ARDS or COPD, ensures supply of tidal volume even in case of leakage of respiratory hose.

A typical pressure waveform of PCV is shown below：

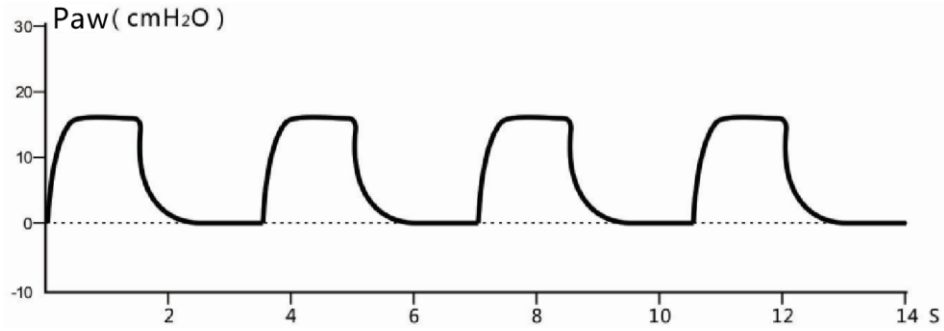


FIGURE 27 PCV

5.5.2 V-A/C and P-A/C

- **CV**

In CV (Controlled Ventilation), which is also known as Mandatory Ventilation, respirator

provides ventilation at preset frequency, in preset tidal volume or at preset pressure, periodically activates inspiration and switches to expiration, completely in place of patient's independent breathing. The patient's breathing modes (frequency, tidal volume, expiration time and inspired air flow rate) are completely controlled by respirator, which supplies all respiratory power. CV is classified into Volume Controlled Ventilation (VCV) and Pressure Controlled Ventilation (PCV).

- **AV**

In AV (Assisted Ventilation), which is activated by decrease of airway pressure (pressure trigger) or change in flow rate (flow rate trigger), the respirator conveys air to the patient at preset tidal volume (or Inspiratory pressure), frequency, inspiration duration and expiration duration.

Popularly speaking, in AV, ventilation of respirator is activated by the patient, and ventilation will not be provided unless the patient inhales. Proper parameters should be set for pressure activation or flow rate activation, in the same way as with CV.

- **A/CV**

A/CV (Assisted/Controlled Ventilation) is a combination of CV and AV, during which, when spontaneous breathing is sufficient and at a frequency higher than the preset one, assisted ventilation is applied; when spontaneous breathing is weak and at an actual respiration frequency equal to the preset one, controlled ventilation is enabled. When the patient takes spontaneous breath, mechanical ventilation is started. When spontaneous breathing is unavailable at a time, mechanical ventilation is automatically switched from assisted ventilation to controlled ventilation. A/CV is a type of IPPV.

- **V-A/CV**

V-A/CV (Volume Assisted/Controlled Ventilation) is based on VCV. Synchronous activation is enabled in expiration stage. When the pressure reaches activation pressure, respirator provides one push of VCV at fixed tidal volume in advance.

A typical pressure waveform of V-A/CV is shown below：

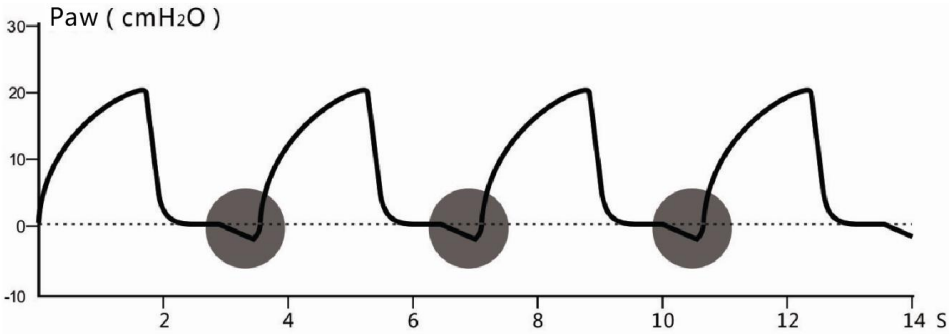


FIGURE 28 V-A/C

- **P-A/CV**

P-A/CV (Pressure Assisted/Controlled Ventilation) is based on VCV. Synchronous trigger is enabled in expiration stage. When the pressure reaches activation pressure, respirator provides one push of PCV at fixed Inspiratory pressure in advance.

A typical pressure waveform of P-A/CV is shown below：

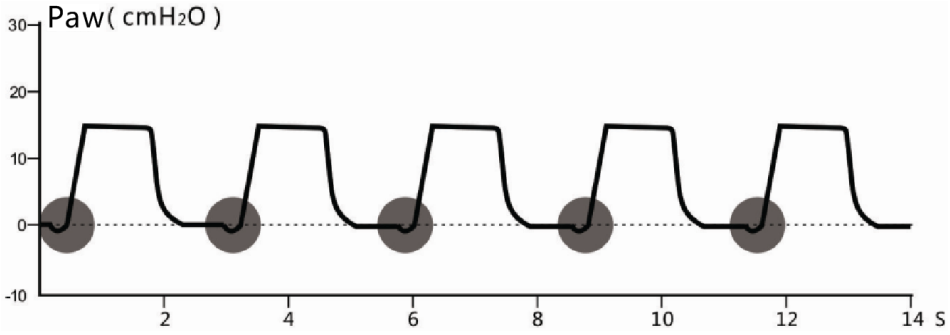


FIGURE 29 P-A/CV

Sign means a deep inhalation at two times of tidal volume based on IPPV once every certain times, which is suitable for patient in long-term need of mechanical ventilation.

Caution:

Sign can be applied only based on V-AC, but not independently.

5.5.3 V-SIMV and P-SIMV

SIMV

SIMV (Synchronized Intermittent Mandatory Ventilation) is a ventilation technology combining spontaneous breathing with IPPV, ensuring effective ventilation to the patient, free of patient-ventilator asynchrony. Proper adjustment can be made to SIMV frequency and flow rate to facilitate patient's respiratory function. Clinically SIMV has become a necessity prior to withdrawal of ventilator.

In V-SIMV (Volume-Constant Synchronized Intermittent Mandatory Ventilation), within a specific activation window, ventilator detects patient's respiratory effort based on preset trigger sensitivity and immediately gives a push of mandatory ventilation at preset tidal volume so as to synchronize delivery of mandatory ventilation with patient's inhaling effort. During duration of activation window, if patient is capable of activating ventilator, an assisted breath will be given; if not, a push of mandatory ventilation will be provided.

A typical pressure waveform of V-SIMV is shown below：

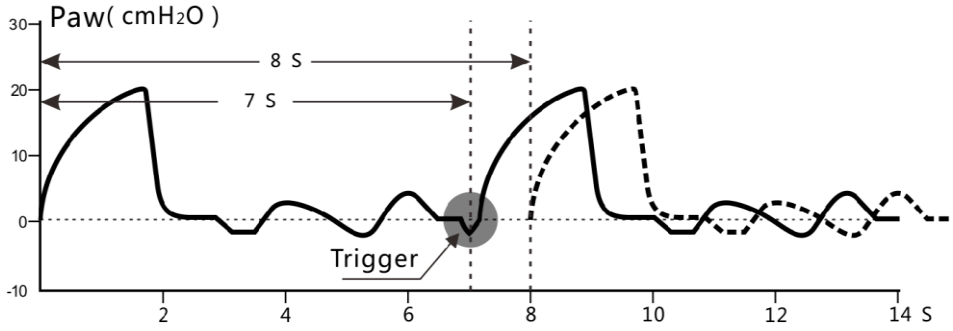


FIGURE 30 V-SIMV

In P-SIMV (Pressure-Constant Synchronized Intermittent Mandatory Ventilation), within a specific activation window, ventilator detects patient's respiratory effort based on window, ventilator detects patient's respiratory effort based on preset activation sensitivity and immediately gives a push of mandatory ventilation at preset pressure so as to synchronize delivery of mandatory ventilation with patient's inhaling effort. During duration of activation window, if patient is capable of activating ventilator, an assisted breath will be given; if not, a push of mandatory ventilation will be provided.

A typical pressure waveform of P-SIMV is shown below：

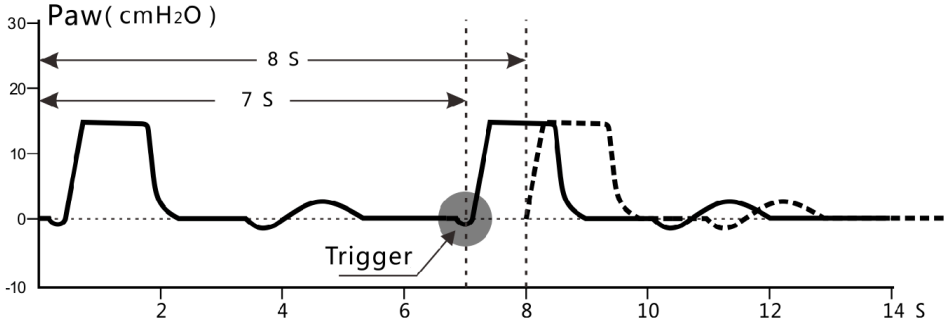


FIGURE 31 P-SIMV

Note: the activation mode in MUSCA x2 ventilator is pressure activation mode.

5.5.4 CPAP

For purpose of CPAP (Continuous Positive Airway Pressure), the ventilator is furnished with a built-in sensitive airway pressure measuring and adjusting system, which adjust positive air flow rate over time and maintain airway pressure substantially at the estimated CPAP. CPAP for intubated patient ranges from 2~5 cmH2O up to 15 cmH2O. CPAP technology can be used only as an assistant breathing means for patients with normal functions of respiratory center and spontaneous breathing, and to exercise respiratory function. CPAP is applicable to hypoxemia mainly resulted from increase of Qsp.

CPAP is a ventilation mode which, based on spontaneous breathing, provide a proper pressure level to maintain positive pressure within the airway throughout the respiratory cycle.

CPAP provides only a certain constant pressure support, not assistant ventilation function. Patient's respiratory patterns including frequency, amplitude, flow rate and tidal volume are all controlled by himself/herself. Therefore, any patient to whom CPAP is applied must have normal function to drive his/her respiratory center and sufficient capacity of spontaneous breathing.

A typical pressure waveform of CPAP is shown below：

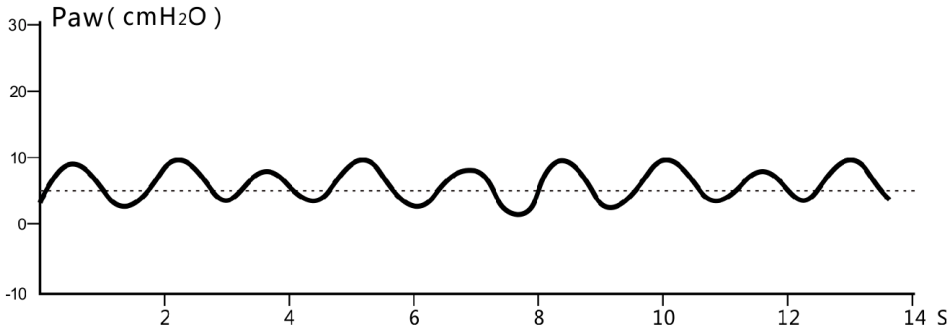


FIGURE 32 CPAP

5.6 Execution of Ventilation

5.6.1 Intubation

Before connecting cannula to patient breathing valve, the patient will usually be intubated (as shown below).

1. Set proper ventilation mode and related respiration parameters based on patient's condition.
2. Connect patient breathing valve to the connector of tracheal cannula.
3. During ventilation, always keep observing the respiration parameters on the screen, so as to ensure your ventilation mode and parameters as set are suitable to the patient.

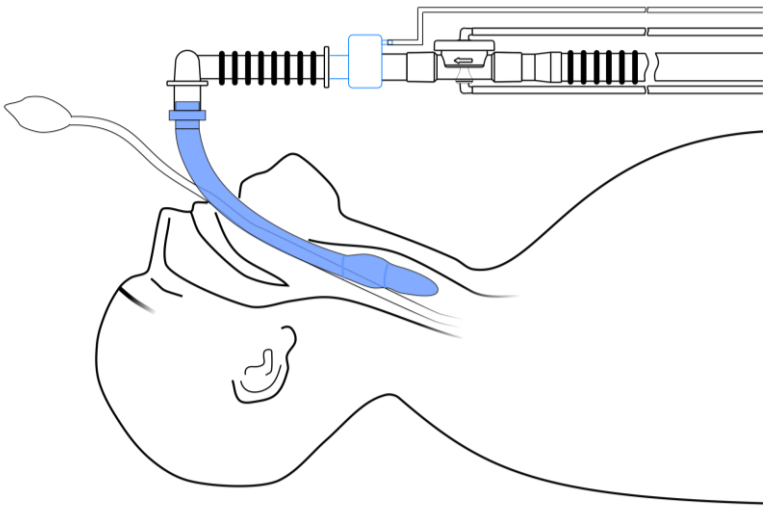


FIGURE 33 Intubation

5.6.2 Respiratory mask

1. Connect respiratory mask to patient breathing valve.

2. Place respiratory mask onto patient's nose and mouth.
3. Keep patient's head backwards and make the mask worn closely against the face.
4. Before wearing the mask, keep patient's respiratory tract unblocked.

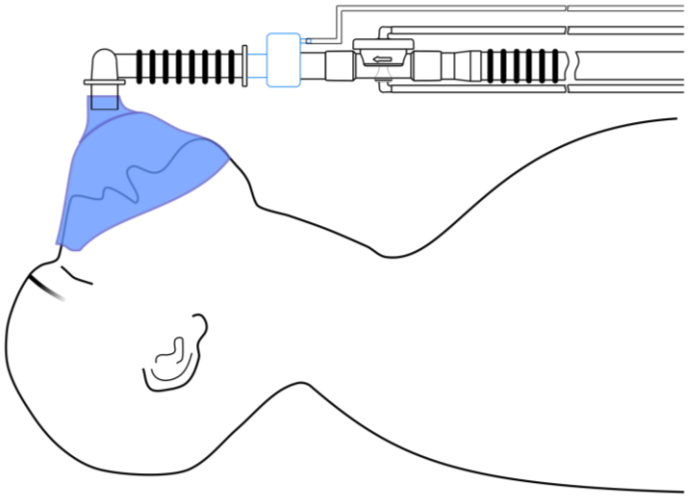


FIGURE 34 Respiratory mask

5.7 Monitoring of Respiration

5.7.1 Real-Time Ventilation Parameters

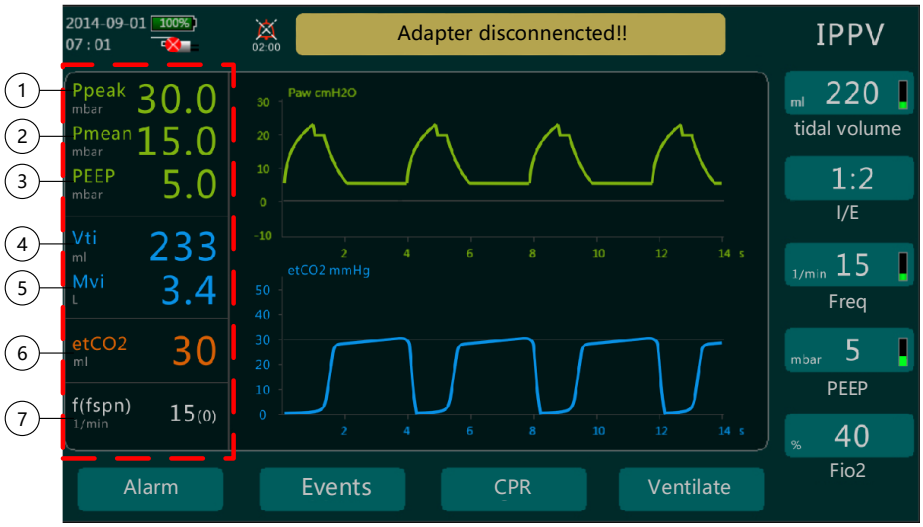


FIGURE 35 Ventilation Parameters

PARTS	PARTS
1 Airway Peak Pressure	**5 Ventilation rate**
2 Average airway pressure	**6 Concentration of carbon dioxide**
3 PEEP	**7 Respiration frequency**
4 Tidal volume	

5.7.2 Waveform Diagram

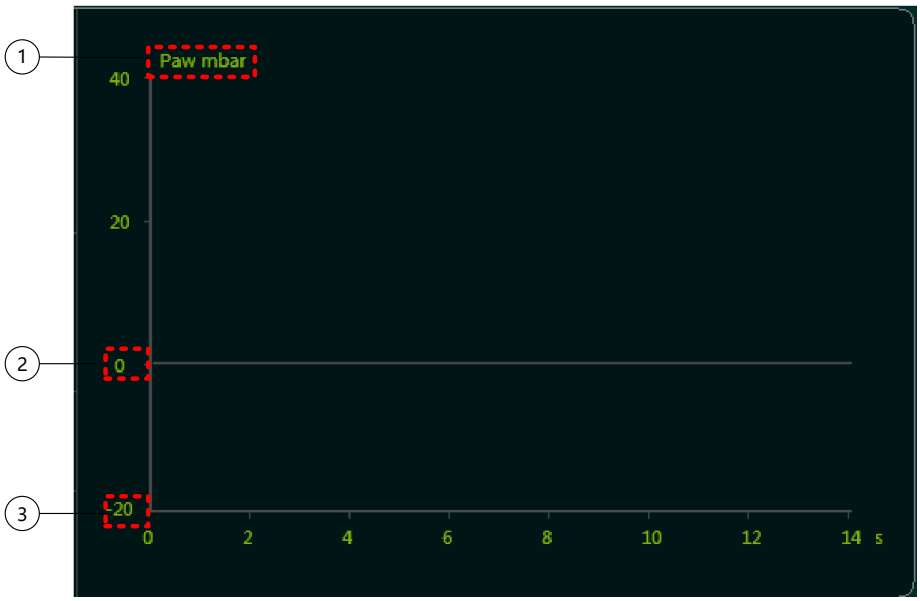


FIGURE 36 Waveform Diagram

PARTS	PARTS
1 Designation unit	**3 Time scale**
2 Pressure scale	

5.8 CPR Ventilation

CPR (Cardiopulmonary Resuscitation) is a procedure used for first-aid treatment. CPR is a first-aid ventilation mode for blood circulation or respiratory arrest and intended to maintain supply to patient's organism and assistance with emission of CO2 from the body. CPR uses volume-constant controlled ventilation. The ventilation rate is set by the user. The preset ventilation rate varies depending on specific type of patient. The vibration frequency varies with operation mode.

The following information are included in CPR procedure:

- **Firstly**: As shown below, click on CPR button in the main interface to open Select Patient Type window with a voice prompt "select patient type".

Three preset tidal volumes correspond to three patient types, as shown below.

SN	Patient Type	Preset Tidal Volume	Preset Time
1	Adults	600ml	I/E of 1:2, and inspiration time of 1s

2	Children	200ml	I/E of 1:2, and inspiration time of 1s
3	Infants	100ml	I/E of 1:2, and inspiration time of 1s

FIGURE 37 Select patient type

- **Secondly:** As shown below, access operation mode selection window with voice prompt "please select operation mode".

Three press ventilation rates correspond to three operation modes, as shown below.

SN	Operation Mode	Press Ventilation Rate	Remark
1	Single-Person Mode	30:2	Not less than 100 presses per minute
2	Double-Person Mode	15:2	
3	Continuous Mode	Continuous press ventilation	

FIGURE 38 Selection of Operating Mode

- **Thirdly:** As shown below, start CPR function - first voice prompt "press for 5 cm or more", then "start pressing", and finally alternative voice prompt " metronom with a speed force " and "ventilation".

  Perform pressing in the rhythm of " metronom with a speed force ".

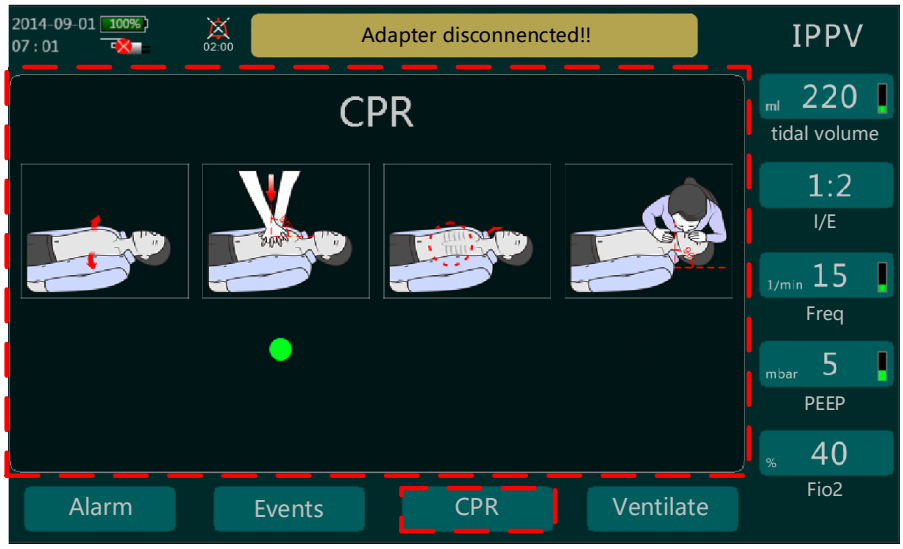


FIGURE 39 CPR

5.9 End Ventilation

Long press Start/Shut Down button for about 3 seconds to shut down ventilator (as shown below).

Attention:

Do not use up any oxygen cylinder. Make sure there is residual pressure inside the cylinder when it is returned so as to prevent entry of wet air into it and corrosion caused thereby.

1. Check the pressure meter on the reducing valve to be aware of the oxygen storage in it. Make replacement with a new oxygen cylinder if the reading on pressure meter is 5 MPa (approx. 725 PSI) or lower.
2. Shut off the outlet valve on the oxygen cylinder.
3. At this moment a voice prompt "shut down oxygen cylinder" will be given.

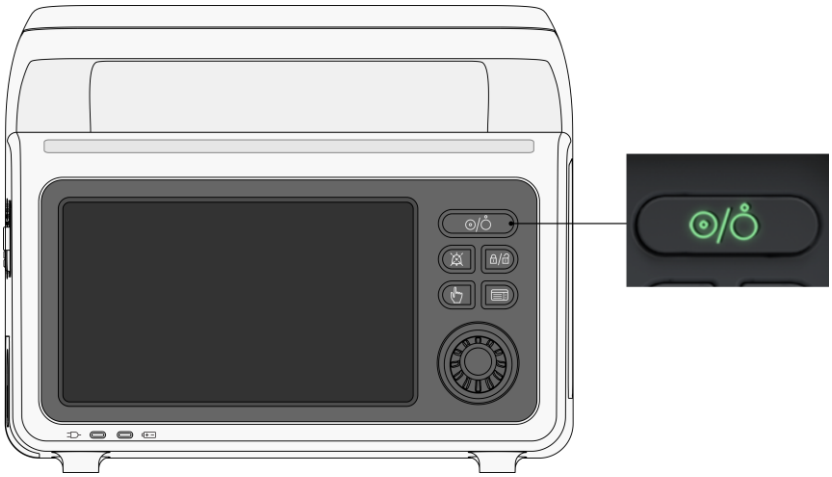


FIGURE 40 Shut down ventilator

5.10 Calculation of Storage Capacity/Operation Duration

- **Storage capacity of oxygen cylinder**

Oxygen capacity = cylinder volume × cylinder pressure.

Example	cylinder volume	X	cylinder pressure	=	oxygen storage capacity
1	10 L		200 Bar		2000 L
1	10 L		100 Bar		1000 L

- **Ventilation Duration**

Tidal Volume VT (L) × Respiration Frequency F (1/min) = Ventilation Rate MV (L/min)

$$\text{Ventilation Duration (min)} = \frac{\text{Oxygen Storage Capacity (L)}}{\text{MV(L / min)}} \times \frac{100\%}{\text{Oxygen Concentration}}$$

- **Example：**

Oxygen Storage Capacity = 1000 L; MV = 11 L / min; oxygen concentration = 100% Calculated as follows：

$$\text{Ventilation Duration (min)} = \frac{1000\ \text{L}}{11\ \text{L/min}} \times \frac{100\%}{100\%} = 91\ \text{min} = 1\ \text{h}\ 31\ \text{min}$$

5.11 Alternative Breathing Apparatus

In case of any malfunction in MUSCA x2 during respiration, use the following alternative breathing apparatus:

- **Respiratory Leather Bag**

1. Remove the patient breathing valve off the cannula or mask.
2. Connect respiratory bag and then perform manual respiration.

- **Failure of Oxygen**

In case of failure of oxygen source for MUSCA x2, the patient can inhale air through patient breathing valve.

5.12 Battery Management

MUSCA x2 is equipped with a built-in chargeable battery whose working time must not be shorter than 5 hours in standard state.

The built-in battery should be recharged for not less than 8 hours, either independently or by the main unit of MUSCA x2 ventilator.

Battery Status Description：

User can view in the main interface whether the battery is connected, being recharged and the battery level, as detailed below：

PARTS	DESCRIPTION
1	indicates that the battery is not connected
2	indicates a battery level of 20 %
3	indicates a battery level of 40 %
4	indicates a battery level of 60 %
5	indicates a battery level of 80 %
6	indicates a battery level of 1000 %

A floating battery level indicates that the battery is being recharged.

If battery indicator LED turns on, it indicates that the battery is connected; the LED going off indicates that the battery is disconnected or run out of; the LED which keeps flashing means that the battery is being recharged.

Caution:

1. When the ventilator is being used in an ambulance, the battery shall not be

recharged. The battery can be recharged only when a power adapter is being used.

2. To ensure normal operation of the battery, it is recommended to recharge and discharge it once every 6 months.

6 Sanitization

MUSCA x2 and its accessories must be sanitized each time after use to keep them in good condition and avoid cross infection. Each time after sanitation, perform functional inspection (refer to Section 7 - Functional Inspection).

6.1 MUSCA x2 Main Unit

Scrub and clean the host simply by soft cloth wet by common water-soluble sanitizer.

While cleaning, prevent the disinfectant from flowing into the respirator. Do not clean the surface of machine by organic solvent.

Caution:

Do not fumigate the whole unit with acidum peraceticum or methanal.

6.2 Respiratory Hose Assembly

Any respiratory hose assembly supplied by aXcent shall be sanitized in accordance with the instructions given below. Any respiratory hose assembly supplied by another manufacturer shall be sanitized in accordance with such manufacturer's instructions.

6.3 Components and Accessories

The mask and any other rubber components shall be sanitized with approved disinfectant.

1. All interior and exterior surfaces of the components shall be adequately soaked without any air bubble. These components can be sanitized for the maximum duration as instructed by the disinfectant manufacturer.
2. After disinfection, clean the components with distilled water to prevent effect of any residual disinfectant on the machine or patient.
3. Place all rubber components in dry air to dry it naturally.
4. Inspect the mask and make replacement for any damage.
5. Reusable respiratory hose and rubber pads of patient breathing valve and respiratory mask can be disinfected with high temperature.

6.4 Valve Fittings

Warning:

Risk of explosion! Do not soak any valve fitting into any disinfectant or other liquid. Disinfect the valve fittings only by wiping with soft cloth. Do not make any liquid enter the reducing valve, or otherwise the valve may explode.

Where disinfection is absolutely necessary, please wipe the reducing valve and the oxygen cylinder with a clean soft cloth, which is dry or slightly soaked with clean water.

6.5 Sanitization Methods

Sanitize MUSCA x2 main unit and its accessories by using the methods as stated below:

Part	Cleaning	Disinfection	Rinsing in Washer	Sterilization
MUSCA x2	Use dry or soaked cloth	By wiping	Not permitted	Not permitted
PEEP hose	Soaked into warm water mixed with mild domestic detergent	With all interior and exterior surfaces soaked into diluted solution for a sufficiently long time without any air bubble; after disinfection, clean all interior and exterior surfaces with distilled water and then dry it	Not permitted	Not permitted
Patient Breathing Valve			Rinsing in temperature below 93 °C is permitted (thermal disinfection in automatic cleaning machine)	Sterilized with hot steam in temperature of 134 °C for 5 minutes by using EN 285 compliant equipment
Reusable respiratory mask				
Reusable respiratory hose				
Oxygen valve fittings	Use dry or soaked cloth	By wiping	Not permitted	Not permitted

7 Functional Inspection

User must perform a functional inspection on the equipment prior to use and after disassembly, or once every six months.

Tips:

When performing functional inspection on MUSCA x2, the respiratory hose and patient breathing valve must be connected.

In case that any malfunction or deviation to any set value is found in functional inspection, the ventilator shall not be used until such malfunction is remove in accordance with Section 8 - Trouble Shooting. If such malfunction cannot be removed, contact aXcent or any professional authorized by it for repair.

The full functional inspection shall include:

- System Air-Tightness Inspection under 7.2；
- Examination of Patient Breathing Valve under 7.3；
- Machine Function Inspection under 7.4.

It is recommended to keep proper inventory of the following spare parts:

- One-way diaphragm of patient breathing valve

7.1 Inspection Cycle

Prior to each use:

- Perform a full functional inspection.

After use or disassembly:

- Clean, disinfect or sterilize the equipment and its components (refer to Section 6 - Sanitization);
- Examine one-way diaphragm in patient breathing valve (refer to 7.3 - Examination of Patient Breathing Valve). The diaphragm shall not be wrinkled, become sticky or twisted.
- Perform a full functional inspection.

As long as being idle

- at least once every six months perform a full functional inspection.

7.2 Inspect System Air-Tightness

1. 1. Open the oxygen cylinder valve slowly. Check the cylinder pressure on the meter of reducing valve. For example, a reading of 2,00PSI indicates sufficient oxygen

storage, while a reading of 1,000PSI indicates that only there is only one half of the full capacity in it. If the pressure reading is less than 725PSI, replace the oxygen cylinder to ensure a ventilation duration of sufficient length.

2. Shut off the oxygen cylinder valve.
3. Observe the reading on the meter of reducing valve for about one minute. If the pointer stays still, it indicates a good air tightness; or otherwise, there is leakage in the cylinder.

Locate and remove leakage:

1. Prepare a dose of soap solution with perfume-free soap.
2. Soak all thread joints and hose couplers into the soap solution. The leakage is located at the position where air bubble appears.
3. Discharge the system pressure by shutting off the oxygen cylinder. Start MUSCA x2 till the reading on cylinder is "0"; and then shut down MUSCA x2.
4. In case of leakage, replace the damaged component.
5. Inspect air tightness again.
6. If the leakage cannot be removed, an overhaul is necessary.

7.3 Examine Patient Breathing Valve

1. Disassemble patient breathing valve.
2. Perform visual inspection on the surfaces of all parts and components for any crack or mechanical damage. Any wrinkled, sticky or twisted one-way diaphragms (in number of three) must be replaced. Replacement is unnecessary during inspection, but any wrinkled, sticky or twisted one-way diaphragms must be replaced to prevent potential serious failure.
3. Re-assembly the patient breathing valve.

Note:

In assembly pay attention to the one-way diaphragms are located at the proper position.

7.4 Machine Function Inspection

In addition to the aforesaid inspections, a simple functional inspection shall be carried on by the dedicated medical personnel on the machine in accordance with the following procedure to prevent any malfunction before use for patient.

Warning:

In case of any problem during inspection, stop using it for the patient!

1. Connect power supply and air supply, and check whether the power supply and air supply operate normally.
2. Start the machine to make it perform self-checking to mainly inspect whether all sensors operate normally.
3. Perform an asphyxia alarm inspection in accordance with the following steps:

a) Set asphyxia alarm time to 15s.

b) Set respiration mode to CPAP and start timing; record the time elapsed before asphyxia alarm is triggered and compare it with the set value. The tested time value should range between 13s and 17s.

4. Check alarm triggered by upper airway pressure limit in accordance with the following steps:

a) Set the ventilator to V-AC ventilation mode.

b) Set Vt to 600ml, I/E to 1: 2, and frequency to 10.

c) Set Pmax to 20cmH20.

d) Block with hand the connection port of Patient Breathing Valve to generate an airway pressure higher than 20cmH20, and at this moment audible and visual alarm should be triggered by the excessive airway pressure. Release hand, and the alarm should be removed about 10 seconds later.

5. Perform an inspection on respiratory system integrity alarm function in accordance with the following steps:

a) Set the ventilator to V-AC ventilation mode.

b) Set Vt to 600ml, I/E to 1: 2, frequency to 10, and Pmax to 30cmH20.

c) With Patient Breathing Valve not connected to model lung, audible and visual alarm should be triggered by such disconnection after two respiratory cycles and the alarm should be removed after the model lung is connected.

6. Check low battery level alarm function in accordance with the following steps:

During self-checking upon start up, low battery level alarm function can be checked.

When oxygen cylinder is opened, If MUSCA x2 is started and operates normally and no alarm is triggered, it indicates that the battery is at sufficient voltage level.

7. Inspect activation pressure function in accordance with the following steps:

a) Set ventilation mode to V-AC.

b) Set activation pressure to -3cmH20.

c) Ventilate air through mask; when negative pressure of inspired air reaches 3cmH20, the respirator should ventilate air in.

8 Trouble Shooting

If any failure cannot be removed, contact aXcent or any professional authorized by it for repair. Stop using the machine in problem to avoid any potential injury.

8.1 Technical Failure

Failure	Cause	Solution
MUSCA x2 fails to start	MUSCA x2 malfunctions	Contact the manufacturer or your dealer for repair
	Battery is exhausted	Recharge battery
Significant oxygen loss	Air supply hose leaks	Locate and eliminate leakage
MUSCA x2 cannot be shut down	Improper operation	Long press Start/Shut Down button for 3 seconds or more
Power supply LED operates unstably	Power supply plug gets loose	Re-connect power supply
Short battery service duration	Battery service life expires	Replace battery with a new one

8.2 Physiological Alarm

Message	Alarm	Cause	Solution
High ventilation rate per min.	High ventilation rate per min.	Exceed the set upper limit of ventilation rate per min.	Examine the patient's condition Check whether the upper limit is set properly
Low ventilation rate per min.	Low ventilation rate per min.	Lower than the set lower limit of ventilation rate per min.	Examine the patient's condition Check whether the lower limit is set properly
Asphyxia	Asphyxia	Asphyxia duration exceeds the set value	Examine the patient's condition Check whether the duration value is set properly
High airway pressure	High airway pressure	Exceeds the set upper limit	Examine the patient's condition
		Airway is blocked	Examine the patient's condition
		Respiratory hose is located improperly	Locate respiratory hose properly

		Pmax is set to a too low value	Set Pmax to a proper value
		Respiratory hose is wound	Check patient's position and make correction as necessary

8.3 System Alarm

Message	Alarm	Cause	Solution
Air source pressure is lower than 2.7 bar	Air source pressure is lower than 2.7 bar	Cylinder valve is not opened or oxygen in the cylinder is exhausted	Open cylinder valve or replace cylinder
		Cylinder is connected improperly	Inspect related connections and make correction as necessary
		Compressed air source is defective	Replace air source
		Ventilator air source hose is wound or pressed	Arrange the air source hose or relieve the hose of any pressure
		Reducing valve is defective	Replace reducing valve
Respiratory system is not connected	Respiratory system is not connected	1. Respiratory hose leaks or falls down. 2. Respiratory mask is worn improperly. 3. Pressure measuring hose leaks or falls down.	Check the connection
		System failure	Carry on an overhaul
Low battery level	Low battery level	Battery level is low	Recharge battery

9 Maintenance

9.1 Routine inspection

Safety inspection shall be performed after each overhaul, and MUSCA x2 shall undergo safety inspection and maintenance regularly.

After each use:

Clean and disinfect reusable respiratory hose and patient breathing valve in accordance with relevant instructions in Section 6.

Once every six months:

Replace filter element in accordance with 9.4 - Replace Filter Element.

Annually:

Clean, disinfect and perform safety inspection on the equipment in accordance with relevant instructions in Section 6. In addition, a general maintenance shall be carried out by the manufacturer or any professionals authorized by it.

Biennially:

Oxygen valve fittings (e.g. reducing valve) shall be maintained by the manufacturer or any professionals authorized by it.

9.2 Battery

MUSCA x2 is equipped with a maintenance-free 7.4V rechargeable lithium battery. It is recommended to periodically recharge it to full (once every 6~12 months, depending on service duration) and then exhaust it. Replace battery in accordance with the following procedure (as shown below).

1. Make sure MUSCA x2 is shut down.
2. Push the clasp in the direction of arrow.
3. Remove the battery off the slot.
4. Push the clasp in the direction of arrow and mount battery into the slot till the clasp is reset in place.

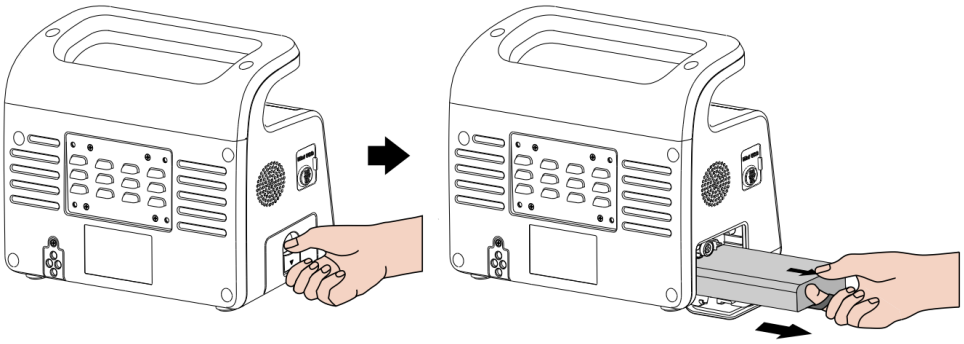


FIGURE 41 Replacement battery

Warning:

1. A battery as specified by aXcent must be used, or otherwise the machine may operate improperly.
2. Short circuiting of battery is prohibited.
3. Heating or burning battery is strictly forbidden.
4. Avoid using battery near any heat source.
5. Wetting battery is prohibited.
6. Avoid recharging battery near any heat source or in direct sunlight.
7. Recharge battery properly with dedicated charger.
8. Do not use the battery with any other battery.
9. Keep the battery out of children's reach.
10. Do not leave the battery mounted in a charger for a long period.
11. Keep leaking battery off fire.
12. Avoid using the battery in strong sunlight.

Tips:

The battery which MUSCA x2 is furnished with is subject to no memory effect. Thus, you can recharge it whenever possible without impairment of its service life, provided that a battery has its inherent lifespan, such as 2 years or 300 recharging times.

9.3 Accessories

For maintenance cycle of MUSCA x2 accessories and maintenance application, refer to related operating instructions.

Oxygen cylinder must be re-checked pursuant to proper guidelines. Expiration date of oxygen cylinder is indicated on the label attached to it.

9.4 Replace Filter

Replace Filter (as shown below):

1. Unscrew the outlet cover with a screwdriver.
2. Take out the old filter element with tweezers.
3. Clean the filter cartridge with medical cotton ball soaked with alcohol.
4. Re-mount a new filter element into the cartridge with tweezers.
5. Re-mount the cover and tighten the screws.

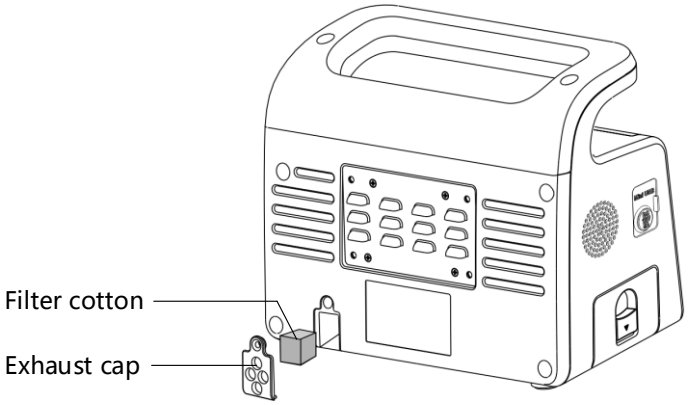


FIGURE 42 Replace Filter

Warning:

The ventilator must not be operated without installation of filter. Or otherwise the equipment performance will be impaired or the equipment is damaged.

9.5 Storage

If MUSCA x2 is left idle for a long time, it is recommended to take the following measures:

1. Clean and disinfect the equipment (refer to Section 6 - Sanitization).
2. Store MUSCA x2 in a dry place.
3. The battery can be mounted in the equipment during storage.

Important:

Even the equipment in storage shall be maintained at the specified maintenance interval before being used.

9.6 Disposal of Waste Equipment

The waste equipment shall be disposed by a certified disposer.

10 MUSCA x2 Supplies Configuration

10.1 Standard Components

SN	Name	Material coding	Unit	Remark
1	MUSCA x2 Main Unit	2.609.00002	Set	English
2	Reusable respiratory hose	2.609.00018	pcs	
3	Big hanger for rubber mask	5.001.00033	pcs	
4	Reusable rubber mask (4#)	5.001.00035	pcs	
5	Rubber headgear (for adults)	5.001.00037	pcs	
6	Power adapter	2.609.00021	pcs	European Standard
7	AC power cable	1.124.00001	pcs	European Standard
8	Rechargeable Li Battery	1.115.00028	pcs	
9	Air source hose	2.601.00046	PCS	2m, with a DISS connector at one end and a quick connector at the other end
10	MUSCA x2 User's Manual	1.601.00137	pcs	English

10.2 Optional Components

SN	Name		Material coding	Unit	Remark
1	ETCO2 module 2.609.00017	Mainstream CO2 module	5.000.00452	PCS	
		Adult adapter (disposable)	5.000.00453	PCS	
		Newborn adapter (disposable)	5.000.00454	PCS	
		Cable fixing slot	5.000.00457	PCS	
2	Single respiratory hose (disposable)		2.609.00019	PCS	

3	Splint	5.000.00168	PCS	
4	Bearing system	2.609.00015	PCS	

Caution：

The specific configuration shall be subject to the packing list.

10.3 Ventilation Mode Configuration List

SN	Ventilation Mode	Options
1	IPPV	●
2	V-A/C	●
3	V-SIMV	●
4	PCV	●
5	P-A/C	●
6	P-SIMV	●
7	CPAP	●
SN	**Other Functions**	**Options**
1	Manual	●
2	CPR	○
Note: ● means standard configuration. ○ means optional configuration.		

11 Technical Parameters

11.1 Medical Devices Management Category

Medical Devices Management Category	
Category	Class-III

11.2 Physical Specifications

Machine size	
size	length：250mm width：200mm height：127mm
Weight	3.4 kg
Display screen	
Types of	TFT color screen
size	7”
Resolution	800 x 480 pixels
Features	With resistor type touch screen control

11.3 Environmental specifications

Operating Environment	
Temperature range	-20℃ ~ 60°C
Humidity range	15% ~ 95%
Air pressure	70kPa ~ 110kPa

11.4 Power Specifications

Power adapter	
Input voltage	100-240V ~
Input frequency	50-60Hz
Input Current	0.7-1.5A
Main unit	
Host input	DC 12V
Total power	≤30VA

11.5 Ventilation mode

Ventilation mode	
Volume-control mode	V-AC, V-SIMV, IPPV
Pressure-control mode	P-AC, P-SIMV, CPAP, PCV
Other mode	CPR, Manual

11.6 Supply specifications

Supply specifications	
Gas supply	Medical oxygen
Gas supply pressure	2.7 ~ 6.0 bar

11.7 Ventilator specifications

Patient breathing valve resistance	
Inspiration	< 6cmH2Oat flow rate of 30, 60 L/min
Expiration	< 6cmH2Oat flow rate of 30, 60 L/min
transport inhaled air inlet	< 6cmH2Oat flow rate of 15, 30 L/min
Max. ventilation flow	
Max. ventilation flow	≥80L/min(@450kPa)
Activation Mode	
Activation Mode	Pressure activation
Control Parameters	
I/E	Adjustable between 9:1 and 1:9 with allowance of ±10%
Respiration frequency	0，1~120bpm with allowance of ±1bpm or ±5%, whichever is the larger
Tidal volume	50~2500mL (ATPD) with allowance of ±30ml or ±15%, whichever is the larger
PEEP/CPAP	0~30cmH20 with allowance of ±2cmH20 or ±10%, whichever is the larger
Inspiratory pressure	5~60cmH20 with allowance of ±2cmH20 or ±10%, whichever is the larger
Conveyed oxygen concentration	40%、100%，±10%（v/v）
Airway pressure limits	15~70cmH20 with allowance of ±2cmH20 or ±10%, whichever is the larger
Activation pressure	-20~20cmH20 with allowance of ±1cmH20 or ±10%, whichever is the larger

Pressure support	0, 3 ~ 35cmH2O, tolerance: ±2cmH2O or ±10%, whichever is the larger.
Pause time ratio	0 ~ 80 %, tolerance: ±10%
Pressure rise time	Slow/normal/fast
Monitoring Parameter	
Tidal volume	0~3000ml with allowance of ±30ml or ±15%, whichever is the larger
Ventilation rate per min.	0~80L/min. with allowance of ±0.5L/min or ±15%, whichever is the larger
Respiration frequency	0 ~120bpm with allowance of ±1bpm or ±5%, whichever is the larger
Airway pressure monitoring	-20~100cmH20 with allowance of ±2cmH20 or ±10%, whichever is the larger
End-expiratory carbon dioxide concentration	0 ~ 150mmHg error: (0 ~ 40 mmHg) ±2mmHg (41 ~ 70 mmHg) ±5% (71 ~ 100 mmHg) ±8% (101 ~ 150 mmHg) ±10%
Mechanical safety valve	
Mechanical safety valve	≤ 100 cmH2O
connecting pipe joint specifications	
Ventilator air source connecting pipe joint specification	Germany type quick connector Quick plug male head： Parker Φ6mm 21SFTF06MXN Quick plug female head： Parker G1/8 21KAAW10MPN The maximum working pressure: 35 bar
Respiratory hose connector specifications	
Respiratory hose connector	Interior ϕ15mm/exterior ϕ22mm
Conversion	
1bar	≈ 100kPa
1cmH2O	≈ 100Pa

Caution：

1. The ventilator may fail when operating not under the conditions as specified by the manufacturer. Make sure that the ventilator operates under the conditions as specified by the manufacturer to ensure stable service.
2. The ventilator may be subject to performance degradation when operating not under the conditions as specified by the manufacturer. Excessive operating pressure may damage interior sensor. Make sure that the ventilator operates within the operating pressure range as specified by the manufacturer to ensure stable service.

11.8 MUSCA x2 Product Structure Diagram

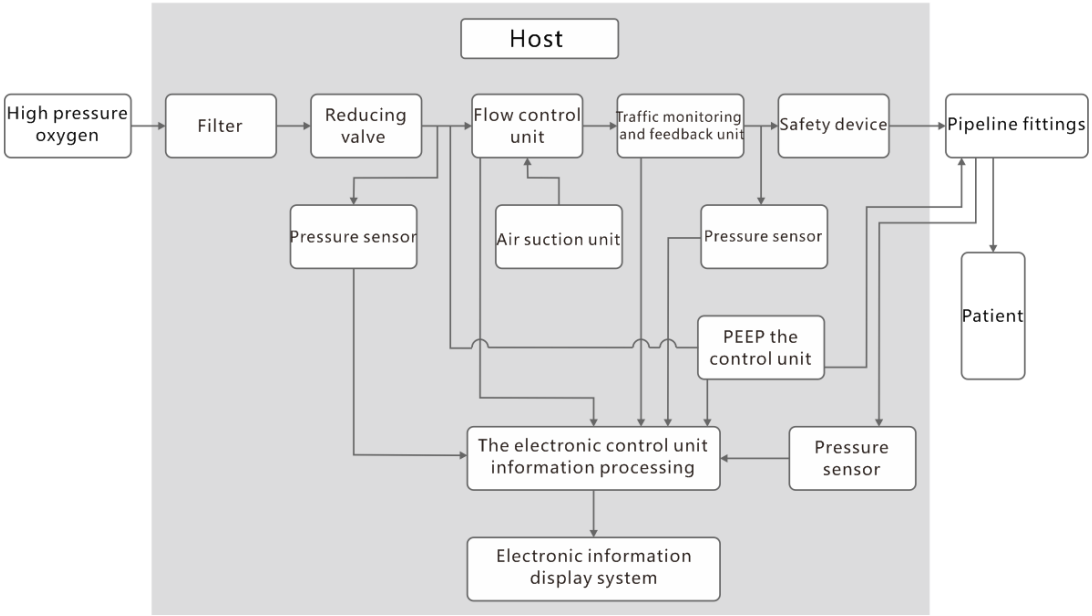


FIGURE 43 MUSCA x2 Product Structure Diagram

11.9 Available Minimum Oxygen Concentration

The oxygen concentration as indicated here is a calculated value, not based on oxygen concentration FiO2 measured with oxygen concentration sensor, but based on the flow rate of inhaled air and output air sum as measured.

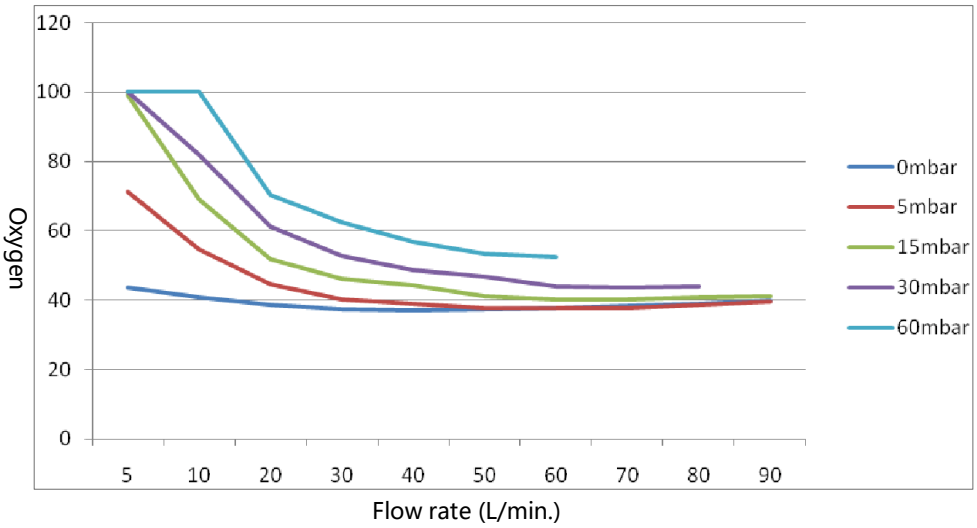


FIGURE 44 Minimum Oxygen Concentration

12 EMC

12.1 EMR Statement

EMR Statement		
MUSCA x2 can be used in the following specific EMR environment, in which user shall ensure to operate this equipment.		
EMR Testing	**Compliance Testing**	**EMR Environment Guide**
Radio frequency radiation (CISPR 11) (GB4824)	Group 1	MUSCA x2 generates radio frequency energy only when operating its internal functions. Therefore, this ventilator emits very small amount of radio frequency radiation and it is unlikely to cause any EMI to electronic equipment nearby.
Radio frequency radiation (CISPR 11) (GB4824)	Category B	MUSCA x2 is applicable in all facilities, including domestic and public LV power supply network directly connected to house.
Harmonic wave radiation (GB 17625.1)	Category A	
Voltage fluctuation and flicker emission (GB 17625.2)	Acceptable	

12.2 EMI Statement - Requirements for All Equipment and Systems

EMI Statement - Requirements for All Equipment and Systems			
MUSCA x2 can be used in the following specific EMR environments, and the user shall ensure to operate this equipment in the following EMR environments.			
EMI Type	**YY0505 Testing Grade**	**Compliance Grade**	**EMR Environment Guide**
ESD (GB/T 17626.2)	Contact discharge: ±8kV Air discharge: ±15kV	Contact discharge: ±8kV Air discharge: ±15kV	The ground shall be of wood, concrete or ceramics. In case of composite paving material, the relative humidity shall be at least 30%.

EFT (GB/T 17626.4)	To power cable: ±2kV To long I/O cable: ±1kV	To power cable: ±2kV To long I/O cable: ±1kV	Power supply grade shall be minimally the grade for typical commercial or medical environment.
Surging (GB/T 17626.5)	DM: ±1kV CM: ±2kV	DM: ±1kV CM: ±2kV	
Power frequency magnetic field (50/60Hz) (GB/T 17626.8)	3A/m	3A/m	Power frequency magnetic field shall be of the horizontal characteristics as in typical commercial or medical environment.
Voltage sag, short interruption and variation (GB/T 17626.11)	< 5%UT (> 95% fall, UT), 0.5 cycle;	< 5%UT (> 95% fall, UT), 0.5 cycle;	Power supply grade shall be minimally the grade for typical commercial or medical environment. It is recommended to use UPS to ensure continuous operation of this product even in case of AC power outage.
	40%UT(60% fall, UT), 5 cycles;	40%UT(60% fall, UT), 5 cycles;	
	70%U T (30% fall, U T), 25 cycles; < 5% UT(> 95% fall, UT), 5s;	70%U T (30% fall, U T), 25 cycles; < 5% UT(> 95% fall, UT), 5s;	

12.3 Guide and Manufacturer Statement – EMI

Guide and Manufacturer Statement - EMI			
MUSCA x2 transport Ventilator is intended for the following EMI environments, and MUSCA x2 purchaser or user shall ensure to operate MUSCA x2 in these EMI environments:			
EMI Test	**IEC 60601 Test Level**	**Compliance Level**	**EM Environment - Guide**
Radio frequency transmission GB/T 17626.6 Radio frequency radiation GB/T 17626.3	3 V (effective value) 150 kHz~80 MHz (except ISM bandsa) 10V (effective value) 150kHz~80MHz (ISM banda) 10V/m 80 MHz ~ 2.5 GHz	3V (effective value) 10V (effective value) 30V/m	Any portable or mobile radio frequency communication equipment shall not be used in a distance closer to any part of MUSCA x2 transport Ventilator (including cable) than as recommended. Such distance is determined based on a formula related to transmitter frequency. Recommended Distance $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$ $d = \left[\frac{12}{V2}\right]\sqrt{P}$ $d = \left[\frac{12}{E1}\right]\sqrt{P}$ 80 MHz~800 MHz $d = \left[\frac{23}{E1}\right]\sqrt{P}$ 800 MHz~2.5 GHz **where,** P : the maximum rated output power (in Watt) of transmitter provided by its manufacturer; *d*: the recommended distance (in meter)[b]. The field strength of fixed radio frequency transmitter is determined based on the survey at EMI location[c], and each frequency range should be lower than Compliance Level[d]. **Interference may occurs near the equipment attached with the following signs.**
Note 1: For frequency of 80MHz and 800MHz, a formula in respect of high frequency should be used.			

Note 2:
As EM transmission is affected by absorption and reflection of buildings, objects and human bodies, these guidelines may not be applicable to all circumstances.

a) ISM bands between 150kHz and 80MHz are 6.765MHz~6.795MHz, 13.553MHz~13.567MHz, 26.957MHz~27.283MHz and 40.66MHz~40.70MHz.
b) ISM bands between 150kHz and 80MHz and compliance levels between 80MHz and 2.5GHz are used to reduce the possibility of interference resulted from mobile/portable communication devices which are accidentally taken into patient's location. For this reason, additional factor 10/3 is used for calculation of recommended distance to the transmitter within these frequency ranges.
c) Theoretically, field strength of fixed transmitters, such as wireless (cellular/cordless) phone and mobile ground radio base station, amateur radio, FA/FM radio broadcast and TV broadcast, cannot be estimated accurately. Evaluation of EMI environment of fixed radio frequency transmitter should take into consideration survey at EM locations. If field strength measured at the place where MUSCA x2 transport Ventilator is located is higher than the aforesaid applicable radio frequency compliance level, then MUSCA x2 transport Ventilator shall be observed to verify its normal operation. If any abnormal property is found, related remedial measure may be required, such as re-adjustment of orientation or position of MUSCA x2 transport Ventilator.
d) Throughout the frequency range of 150kHz~80MHz, the field strength should be lower than 3V/m.

12.4 Recommended isolation distance

Recommended distance between portable and mobile RF communication equipment and MUSCA x2 transport Ventilator				
MUSCA x2 transport Ventilator is intended for use in RFI-controlled EMI environments. Based on the maximum rated power of related communication equipment, purchaser or user can prevent EMI by maintaining the minimum distance between portable and mobile RF communication equipment and MUSCA x2 transport Ventilator as recommended below.				
Max. Output Power of Transmitter (W)	Distance (m) for Transmitters of Various Frequencies			
	150 kHz~80 MHz (except ISM bands) d = $1.17\sqrt{P}$	150 kHz~80 MHz (ISM bands) d = $1.2\sqrt{P}$	80 MHz ~ 800 MHz d = $0.4\sqrt{P}$	800 MHz~2.5 GHz d = $0.767\sqrt{P}$
0.01	0.12	0.12	0.04	0.08
0.1	0.38	0.38	0.13	0.24
1	1.2	1.20	0.40	0.77
10	3.8	3.80	1.30	2.40
100	12.00	12.00	4.00	7.70
For any maximum rated output power which is not listed in the table above, the recommended distance d (in meter) can be determined based on the formula in the corresponding volume of transmitter frequency, where p is the maximum rated output power in (Watt) of transmitter provided by its manufacturer.				

Note 1: For frequency of 80MHz and 800MHz, a formula in respect of high frequency should be used. **Note 2:** ISM bands between 150kHz and 80MHz are 6.765MHz~6.795MHz, 13.553MHz~13.567MHz, 26.957MHz~27.283MHz and 40.66MHz~40.70MHz. **Note 3:** Additional factor 10/3 is used for calculation of recommended distance to the transmitter within frequency ranges of 150kHz ~ 80MHz and 80MHz~2.5GHz, so as to reduce the possibility of interference resulted from mobile/portable communication devices which are accidentally taken into patient's location. **Note 4:** As EM transmission is affected by absorption and reflection of buildings, objects and human bodies, these guidelines may not be applicable to all circumstances.

12.5 Information on MUSCA x2 Patient's Physiological Signals

Information on MUSCA x2 Patient's Physiological Signals
The physiological frequency range of the patients for whom MUSCA x2 transport Ventilator is used is between 5bpm and 40bpm.
Warning: **Operation of the equipment or system at a frequency lower than the aforesaid range may cause incorrect results.**

12.6 Basic EMC Properties of MUSCA x2 transport Ventilator

Basic EMC Properties of MUSCA x2 transport Ventilator	
MUSCA x2 transport Ventilator will operate based on the parameters as set. For more details see Section 11 in the manual. User can give alarm based on real-time monitoring of operation state of MUSCA x2 transport Ventilator and ensure accuracy of the following parameters in EMC environment instructed for MUSCA x2 transport Ventilator.	
I/E	Adjustable between 9:1 and 1:9 with allowance of ±15%
Ventilation rate per min. (MV)	1~45L/min. with allowance of ±0.5L/min or ±20%, whichever is the larger
Airway pressure monitoring	-20~100cmH20 with allowance of ±2cmH20 or ±15%, whichever is the larger
Activation pressure	-20~20cmH20 with allowance of ±1cmH20 or ±15%, whichever is the larger
Parameters of EMC Cable Material	
Adapter input power cable	0.8±0.01m

Adapter output power cable	1.45+0.05m

Caution:

- EMC of the location where this environment is mounted and used shall be adequately take into consideration in accordance with the said guidelines.
- Any equipment on or near MUSCA x2 ventilator may still cause interference with MUSCA x2 even though it is CISPR compliant, so user shall verify whether MUSCA x2 operates normally before using it for patent.
- Application of any unapproved part or component to this equipment may impair its electromagnetic immunity and increase its EME.

13 Warranty

1. Within two years of purchase, any quality defect occurring in proper operation pursuant to this manual will be subject to aXcent's repair service free of charge. If the shelf life as labeled on the product is less than two years, this warranty will become invalid with expiration of such shelf life.
2. Upon request for repair service, a certificate of purchase attached with name of the seller and date of purchase must be provided.
3. This warranty becomes invalid in one of the following cases:

- Failure to observe related instructions
- Improper operation
- Improper use or handling
- Repair on the equipment by any unauthorized personnel
- Occurrence of force majeure, such as lightning stroke
- Damage during delivery to the manufacture resulted from improper packaging
- Poor maintenance
- Wear resulted from excessive use or normal wear; parts to which this item is applicable include:
- Filter
- Battery
- disposable article
- use of any spare part other than recommended.

4. aXcent will not be responsible for any damage not resulted from intentional or gross negligence and body injury caused by minor fault.
5. aXcent will take no responsibility for any problem arising after service life of this product has expired.
6. aXcent reserves the right to remove any defect, supply deficiency-free goods or properly reduce purchase price at its own discretion.
7. In case that any request for repair service is rejected, the freight shall not be at aXcent's cost.
8. Any statutory warranty shall be exempt of the aforesaid restrictions.

14 Classification of Toxic/Harmful Substances

Name & Content of Toxic/Harmful Substances							
Name of Part		**Cadmium (Cd)**	**Mercury (Hg)**	**Lead (Pb)**	**Hexavalent Chrome (Cr-VI)**	**PBB**	**PBDE**
Display Screen		×	×	×	×	×	×
Lithium Battery		×	×	×	×	×	×
Main Unit of Anaesthesia Breathing System		○	○	×	×	○	○
Packing Material		○	×	×	○	×	×
Main Unit	PCBA	○	○	×	○	○	○
	Interior Connecting Wires	○	○	○	○	○	○
	Machined Parts	○	○	○	×	○	○
Enclosure	Button	○	○	○	○	○	○
	Label	○	○	○	○	○	○
	Front Cover	○	○	○	○	○	○
	Rear Cover	○	○	○	○	○	○
Accessories	Air Hose	○	○	○	○	○	○
	Mask	○	○	○	○	○	○
	Corrugated Tube Assembly	○	○	○	○	○	○
	Air Source Hose Assembly	○	○	○	○	○	○
	Reservoir Bag	○	○	○	○	○	○
	Power Cable	○	○	○	○	○	○
	Connectors	○	○	○	×	○	○
	Vaporizer	○	○	×	○	○	○
	Jinn Bottle	○	○	○	○	○	○
	Steel Cylinder	○	×	×	○	○	○
	Flow Rate Sensor	○	○	○	○	○	○
	Oxygen Sensor	○	○	×	○	○	○

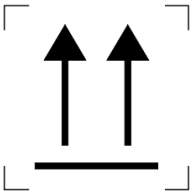
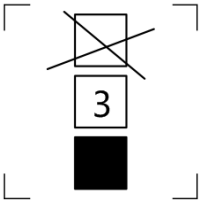
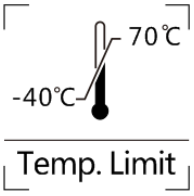
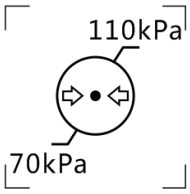
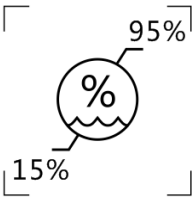
	CO2 Monitor	○	○	×	○	○	○

×: means that content of the harmful substance or element in at least one homogeneous material composing related part exceeds the limit as stipulated in SJ/T11363-2006.

○: means that the content of the harmful substance or element in all homogeneous material composing related part is within the limit as stipulated in SJ/T11363-2006.

15 Storage and Transport

The packaged product can be transported on road, by air or by train. Impact, extreme vibration and humidity shall be prevented during transportation.

Graphics	DESCRIPTION	Graphics	DESCRIPTION
	This way up		Handle with care
	Keep dry		Stacking limit：3
	Temp.Limit：-40~70℃		
	Pressure range：70kPa~110kPa		
	Humidity range：15%~95% Non-condensing		

Warning：

When it is moved out from a storage condition not meeting the foregoing, this equipment shall be placed in a standard environment for at least 8 hours before being used.

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axcent medical

Intensive Care and Transport Ventilator Solutions

www.axcentmedical.com

LYRA x1 **Best performing and versatile ventilation for hospital applications**

A compact turbine driven ventilator with multi-function, covers the non-invasive and invasive ventilation, and is suitable for treatment of most patient type. LYRA x1 is versatile throughout hospital and transport. Comprehensive ventilating modes, including APRV, PRVC, NIV are available for all your demands and for all type of patients from neonatal to adult.

A collapsible high-resolution touch-screen display makes LYRA x1 mounted on a trolley your choice for ICU applications, as well as a high performance ventilator throughout hospital and transport.

The innovative expiration valve disassembling concept brings more ease and efficiency for the sterilization process. As your versatile assistant, LYRA x1 is configured with O2 therapy, P-V tool, a lung titrating gold standard, etc.

www.axcentmedical.com

LYRA x1

Technical Specifications

Physical Specification

Dimensions: 336 mm x 330 mm x 345 mm
(L x W x H): 664 mm x 600 mm x 1370 mm
(with trolley)
Weight: Approximately 9.5 kg,
Approximately 31.0 kg (with trolley)

Screen

Display Size: 12.1 Color active matrix TFT touch
Display Resolution (H) x (V): 1280 x 800 pixels
Brightness: Adjustable

Ventilation Specifications

Patient Type: Adult, Pediatric, Neonate

Invasive Ventilation Mode:

VCV (Volume Control Ventilation)
PCV (Pressure Control Ventilation)
VSIMV (Volume Synchronized Intermittent Mandatory Ventilation)
PSIMV (Pressure Synchronized Intermittent Mandatory Ventilation)
CPAP/PSV (Continuous Positive Airway Pressure/Pressure Support Ventilation)
PRVC (Pressure Regulated Volume Control)
V + SIMV (PRVC + SIMV)
BPAP (Bilevel Positive Airway Pressure)
APRV (Airway Pressure Release Ventilation)
Apnea Ventilation

Non-invasive Ventilation Mode:

PCV (Pressure Control Ventilation)
PSIMV (Pressure Synchronized Intermittent Mandatory Ventilation)
CPAP/PSV (Continuous Positive Airway Pressure/Pressure Support Ventilation)
BPAP (Bilevel Positive Airway Pressure)
APRV (Airway Pressure Release Ventilation)

Controlled Parameters

O_2%: 21-100% (increments of 1%)
VT (Tidal Volume): Adult: 100-2000 mL (increments of 10 mL) / Pediatric: 20-300 mL / Neonate: 2-300 mL (increments of 1 mL)
f (Ventilation frequency): 1-80 bpm / Neonate: 1-150 bpm (increments of 1 bpm)
fSIMV (Ventilation frequency in SIMV mode): 1-80 bpm / Neonate: 1-150 bpm (increments of 1 bpm)
I:E range: 4:1-1:10 (increments of 0.5)
Tinsp (Inspiratory time): 0.20-10 s (increments of 0.05 s)
Tslope (Time of Pressure Rising): 0-2.00 s (increments of 0.05 s)
Thigh: 0.2-30 s (increments of 0.1 s)
Tlow: 0.2-30 s (increments of 0.1 s)
Tpause: 5%-60% (increments of 1%), Off
ΔPinsp: 5-60 cm H_2O (increments of 1 cm H_2O)
ΔPsupp: 0-60 cm H_2O (increments of 1 cm H_2O)
Phigh: 0-60 cm H_2O (increments of 1 cm H_2O)
Plow: 0-45 cm H_2O (increments of 1 cm H_2O)
PEEP: 1-45 cm H_2O (increments of 1 cm H_2O), Off
Flow trigger: 0.5-15 L/min (increments of 0.1 L/min)
Pressure trigger: -10 to -0.5 cm H_2O (increments of 0.5 cm H_2O)
Exp% (Expiration termination level): 10-85% (increments of 5%), Auto

axcent medical

LYRA x1

Technical Specifications

Apnea Ventilation

Vtapnea: Adult: 100-2000 mL (increments of 10 mL) / Pediatric: 20-300 mL / Neonate: 2-300 mL (increments of 1 mL)
ΔPapnea: 5-60 cm H_2O (increments of 1 cm H_2O)
Fapnea: 1-80 bpm (increments of 1 bpm)
Apnea Tinsp: 0.20-10 s (increments of 0.05 s)

Sigh

Sigh Switch: On, Off
Interval: 20 s-180 min (increments of 1 s from 20 to 59 s, increments of 1 min from 1 to 180 min)
Cycles Sigh: 1-20 (increments of 1)
Δint.PEEP: 1-45 cm H_2O (increments of 1 cm H_2O), Off

Synchronized Tube Resistance Compliance

Tube Type: ET Tube, Trach Tube, Disable STRC
Tube I.D.: Adult: 5.0 -12.0 mm (increments of 0.5 mm) / Pediatric: 2.5 - 8.0 mm (increments of 0.5 mm)
Compensate: 0-100% (increments of 1%)
Expiration Compliance Switch: On, Off

Monitored parameters

Numeric:

Paw	Vte	Cdyn
Ppeak	VTi	Cstat
Pplat	Oxygen concentration	Rcexp
Pmean	VTe spn	WOB
PEEP	VTe/IBW	RSBI
Insp Flow	ftotal	NIF
Exp Flow	fmand	P0.1
MV	fspn	PEEPi
MV leak	Re	
MV spn	Ri	

Continuous Flow (O Therapy)

Real time Graphics:
Pressure-time waveforms: Paw-Volume Loop
Flow-time waveforms: Flow-time Loop
Volume-time waveforms: Paw-Flow Loop

Control Accuracy

O_2%: ±(3 vol.% +1% of setting)
TV: ±(10 mL +10% of setting) (BTPS)
Tinsp: ±0.1 s or ±10% of setting, whichever is greater
I: E 2:1 to 1:4: ±10% of setting, other range: ±15% of setting
f: ±1 bpm
fSIMV: ±1 bpm
Tslope: ±(0.2 s + 20% of setting)
PEEP: ±(2.0 cm H_2O + 5% of setting)
ΔPinsp: ±(2.0 cm H_2O + 5% of setting)
ΔPsupp: ±(2.0 cm H_2O + 5% of setting)
Phigh: ±(2.0 cm H_2O + 5% of setting)
Plow: ±(2.0 cm H_2O + 5% of setting)
Thigh: ±0.2 s or ±10% of setting, whichever is greater
Tlow: ±0.2 s or ±10% of setting, whichever is greater
Pressure Trigger: ±(1.0 cm H_2O + 10% of setting)
Flow Trigger: ±(1.0 L/min + 10% of setting)
Δint.PEEP: ±(2.0 cm H_2O + 5% of setting)
Exp%: ±10%
fapnea: ±1 bpm
ΔPapnea: ±(2.0 cm H_2O + 5% of setting)
Tvapnea: ±(10 mL + 10% of setting) (BTPS)
Apnea Tinsp: ±0.1 s or ±10% of setting, whichever is greater

Monitoring Accuracy

Airway pressure (Ppeak, Pplat, Pmean, PEEP, PAP, EPAP): ±(2 cm H_2O + 4% of the actual reading)
Tidal Volume: (Tvi, Tve, TVe/IBW, TVe spn):
0 ml-100 ml: ±(10 ml + 3% of the actual reading) (BTPS)
100 ml-4000 ml: ±(3 ml +10% of the actual reading) (BTPS)
Minute Volume (MV, MVspn, Mvleak):
±0.3 L/min or ±8% of the actual reading, whichever is greater (BTPS)
Frequency (ftotal, fmand, fspn): ±5% of reading or ±1bpm, whichever is greater
Inspired Oxygen (FiO_2): ±(2.5 vol.% + 2.5% of the actual reading)
Resistance: 0 to 50: ±10 cm H_2O/L/s
Other range: 50% of the actual reading
Compliance: 25% of the actual reading or ±10 ml/cm H_2O, whichever is greater
RSBI: 0 to 1000 1/(Lmin): 15% of the actual reading or ±20 1/(Lmin)
WOB: -
NIF: ±(2 cm H_2O + 4% of the actual reading)
P0.1: ±(2 cm H_2O + 4% of the actual reading)
PEEPi: -
Rcexp: -

Alarm settings

Tidal Volume: High / Low
Minute Volume: High / Low
Airway pressure: High / Low
Frequency: High / Low
Inspired Oxygen (FiO2): High / Low
etCO2: High / Low
Apnea alarm time: 5-60 s

Trend

Type: Tabular, Graphic
Length: 72 hours
Content: Monitor Parameters, Setting Parameters (Setting Ventilation mode and Parameters)

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Technical Specifications

O_2 Therapy

Controlled Parameters
O_2%: 21-100% (increments of 1%)
Flow: 4-60 L/min
Controlled Accuracy
O_2%: ±(3 vol.% +1% of setting)
Flow: ±(2 L/min +10% of setting) (BTPS)

Environmental specifications

Temperature: 5-40 °C (operating); -20 to 60 °C (storage and transport, O_2sensor: -20 to 50 °C)
Relative Humidity: 10-95% (operating); 10-95% (storage and transport)
Barometric Pressure: 62-106 kPa (operating); 50-106 kPa (storage and transport)

Power Battery Backup

External AC power supply
Input voltage: 100-240 V
Input frequency: 50/60 Hz
Input current: 2.5 A Max
Fuse: T2.5 AH/250 V
Internal battery
Number of batteries: One or Two (Optional)
Battery type: Build-in Lithium-ion battery, 11.25 VDC, 6400 mAh
Battery run time: 3 hours (Powered by one new fully-charged battery in standard working condition), 6 hours (powered by two new fully-charged batteries in standard working condition).

Others

Communication interface: RS-232, Ethernet, USB port, CO2 analyzer connector
Gas supply: O2
(HPO) Oxygen connector: NIST (DISS optional)
Gas supply pressure: 280-600 kPa

LYRA x2 **Top notch performance of Non-Invasive and Invasive Ventilation**

LYRA x2 is a premium non-invasive turbine driven ventilator with no compromise on the performance in invasive ventilation.

User can easily switch between NIV- and IV-modes by UI operation only.

Comprehensive parameter monitoring describes the full scenario of patient's status to the care giver.

In a busy ICU it is imperative to give the desired mechanical ventilation to the patient.

An 18.5 inch vertical layout touchscreen display makes operating of the ventilator smooth & easy.

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LYRA x2

Technical Specifications

Physical Specification

Dimensions: 327 mm x 310 mm x 493 mm
(L x W x H): 664 mm x 600 mm x 1520 mm
(with trolley)
Weight: Approximately 12.0 kg, Approximately 33.0 kg (with trolley)

Screen

Display Size: 18.3 Color active matrix TFT touch
Display Resolution (H) x (V): 1080 x 1980 pixels
Brightness: Adjustable

Ventilation Specifications

Patient Type: Adult, Pediatric, Neonate
Invasive Ventilation Modes:
VCV (Volume Control Ventilation)
PCV (Pressure Control Ventilation)
VSIMV (Volume Synchronized Intermittent Mandatory Ventilation)
PSIMV (Pressure Synchronized Intermittent Mandatory Ventilation)
CPAP/PSV (Continuous Positive Airway Pressure/Pressure Support Ventilation)
PRVC (Pressure Regulated Volume Control)
V + SIMV (PRVC + SIMV)
BPAP (Bilevel Positive Airway Pressure)
APRV (Airway Pressure Release Ventilation)
Apnea Ventilation
Non-invasive Ventilation Modes:
CPAP (Continuous Positive Airway Pressure)
PCV (Pressure Control Ventilator)
PPS (Proportional Pressure Support)
S/T (Spontaneous and Timed)
VS (Volume Support)

Controlled Parameters

O_2%: 21-100% (increments of 1%)
VT (Tidal Volume): Adult: 100-2000 mL (increments of 10 mL) / Pediatric: 20-300 mL / Neonate: 2-300 mL (increments of 1 mL)
f (Ventilation frequency): 1-80 bpm / Neonate: 1-150 bpm (increments of 1 bpm)
fSIMV (Ventilation frequency in SIMV mode): 1-80 bpm / Neonate: 1-150 bpm (increments of 1 bpm)
I:E range: 4:1-1:10 (increments of 0.5)
Tinsp (Inspiratory time): 0.20-10 s (increments of 0.05 s)
Tslope (Time of Pressure Rising): Thigh 0-2.00 s (increments of 0.05 s)
Tlow: 0.2-30 s (increments of 0.1 s)
Tpause: 0.2-30 s (increments of 0.1 s)
ΔPinsp: 5%-60 cm H_2O (increments of 1 cm H2O), Off
ΔPsupp: 0-60 cm H_2O (increments of 1 cm H_2O)
Phigh: 0-60 cm H_2O (increments of 1 cm H_2O)
Plow: 0-45 cm H_2O (increments of 1 cm H_2O)
PEEP: 1-45 cm H_2O
(increments of 1 cm H_2O), Off
Flow trigger: 0.5-15 L/min
(increments of 0.1 L/min)
Pressure trigger: -10 to -0.5 cm H_2O
(increments of 0.5 cm H_2O)
Exp% (Expiration termination level): 10-85% (increments of 5%), Auto
CPAP: 4-25 cm H_2O (increments of 1 cm H_2O)
EPAP: 4-25 cm H_2O (increments of 1 cm H_2O)
IPAP: 4-20 cm H_2O (increments of 1 cm H_2O)

Rise time: 1-5 (increments of 1)
Ramp time: 5-45 min (increments of 5 min), Off
Min P (VS minimum IPAP): 5-30 cm H_2O (increments of 1 cm H_2O)
Max P (VS maximum IPAP): 6-40 cm H_2O (increments of 1 cm H_2O)
Max P (PPV maximum pressure limit): 5-40 cm H_2O (increments of 1 cm H_2O)
Max V (PPV maximum volume limit): 200-3500 mL (increments of 5 ml)
Max E: 0-100 cm H_2O/L (increments of 1 cm H_2O/L)
Max R: 0-50 cm H_2O/L (increments of 1 cm H_2O/L)
PPV%: 0%-100% (increments of 1%)

Apnea Ventilation

Vtvapnea: Adult: 100-2000 mL (increments of 10 mL) / Pediatric: 20-300 mL / Neonate: 2-300 mL (increments of 1 mL)
ΔPapnea: 5-60 cm H_2O (increments of 1 cm H_2O)
Fapnea: 1-80 bpm (increments of 1 bpm)
Apnea Tinsp: 0.20-10 s (increments of 0.05 s)

Sigh

Sigh Switch: On, Off
Interval: 20 s-180 min (increments of 1 s from 20 to 59 s, increments of 1 min from 1 to 180 min)
Cycles Sigh: 1-20 (increments of 1)
Δint.PEEP: 1-45 cm H_2O (increments of 1 cm H_2O), Off

Synchronized Tube Resistance Compliance

Tube Type: ET Tube, Trach Tube, Disable STRC
Tube I.D.: Adult: 5.0-12.0 mm (increments of 0.5 mm) / Pediatric: 2.5-8.0 mm (increments of 0.5 mm)
Compensate: 0-100% (increments of 1%)
Expiration Compliance Switch: On, Off

Monitored parameters

Numeric:

Paw	Oxygen concentration	WOB
Ppeak	VTe spn	RSBI
Pplat	VTe/IBW	NIF
Pmean	f	P0.1
PEEP	ftotal	PEEPi
Insp Flow	fmand	PIP
Exp Flow	fspn	EPAP
MV	Re	Pt.Trig
MV leak	Ri	Pt.leak
MV spn	Cdyn	Tot.leak
Vte	Cstat	Continuous Flow (O_2 Therapy)
VTi	Rcexp	

Real time Graphics:
Pressure-time waveforms: Paw-Volume Loop
Flow-time waveforms: Flow-time Loop
Volume-time waveforms: Paw-Flow Loop

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LYRA x2

Technical Specifications

Control Accuracy

O_2%: ±(3 vol.% + 1% of setting)
TV: ±(10 mL + 10% of setting) (BTPS)
Tinsp: ±0.1 s or ±10% of setting, whichever is greater
I: E: 2:1 to 1:4: ±10% of setting, other range: ±15% of setting
f: ±1 bpm
fSIMV: ±1 bpm
Tslope: ±(0.2 s + 20% of setting)
PEEP: ±(2.0 cm H_2O + 5% of setting)
ΔPinsp: ±(2.0 cm H_2O + 5% of setting)
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Phigh: ±(2.0 cm H_2O + 5% of setting)
Plow: ±(2.0 cm H_2O + 5% of setting)
Thigh: ±0.2 s or ±10% of setting, whichever is greater
Tlow: ± 0.2 s or ±10% of setting, whichever is greater
Pressure Trigger: ±(1.0 cm H_2O + 10% of setting)
Flow Trigger: ±(1.0 L/min + 10% of setting)
Δint.PEEP: ±(2.0 cm H_2O + 5% of setting)
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CPAP: ±(2.0 cm H_2O + 5% of setting)
EPAP: ±(2.0 cm H_2O + 5% of setting)
IPAP: ±(2.0 cm H_2O + 5% of setting)
Rise time: -
Ramp time: ±1 s
Min P (VS minimum IPAP): ±(2.0 cm H_2O + 5% of setting)
Max P (VS maximum IPAP): ±(2.0 cm H_2O + 5% of setting)
Max P (PPV maximum pressure limit): ±(2.0 cm H_2O + 5% of setting)
Max V (PPV maximum volume limit): ±15% of setting
Max E: -
Max R: -
Fapnea: ±1 bpm
ΔPapnea: ±(2.0 cm H_2O + 5% of setting)
Tvapnea: ±(10 mL + 10% of setting) (BTPS)
Apnea Tinsp: ±0.1 s or ± 10% of setting, whichever is greater

Monitoring Accuracy

Airway pressure (Ppeak, Pplat, Pmean, PEEP, PAP, EPAP): ±(2 cm H_2O + 4% of the actual reading)
Tidal Volume (Tvi, Tve, TVe/IBW,TVe spn):
0 ml -100 ml: ± (10 ml+3% of the actual reading) (BTPS) / 100 ml - 4000 ml:
±(3 ml + 10% of the actual reading) (BTPS)
Minute Volume (MV, MVspn, Mvleak): ±0.3 L/min or ±8% of the actual reading, whichever is greater (BTPS)
Frequency (ftotal, fmand, fspn): ±5% of reading or ±1 bpm, whichever is greater
Inspired Oxygen (FiO_2): ±(2.5 vol.% + 2.5% of the actual reading)
Resistance: 0 to 50: ±10 cm H_2O/L/s Other range: 50% of the actual reading
Compliance: 25% of the actual reading or ±10 ml/cm H_2O, whichever is greater
RSBI: 0 to 1000 1/(Lmin): 15% of the actual reading or ± 20 1/(Lmin)
WOB: -
NIF: ± (2 cm H_2O + 4% of the actual reading)
P0.1: ± (2 cm H_2O + 4% of the actual reading)
PEEPi: -
Rcexp: -

Alarm settings

Tidal Volume: High / Low
Minute Volume: High / Low
Airway pressure: High / Low
Frequency: High / Low
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etCO2: High / Low
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Power Battery Backup

External AC power supply
Input voltage: 100-240 V
Input frequency: 50/60 Hz
Input current: 2.5 A Max
Fuse: T2.5 AH/250 V
Internal battery
Number of batteries: One or Two (Optional)
Battery type: Build-in Lithium-ion battery, 11.25 VDC, 6400 mAh
Battery run time: 3 hours (Powered by one new fully-charged battery in standard working condition) / 6 hours (Powered by two new fully-charged battery in standard working condition)

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Technical Specifications

Others

Communication interface: RS-232, Ethernet, USB port, CO_2 analyzer connector
Gas supply: O^2
(HPO) Oxygen connector: NIST (DISS optional)
Gas supply pressure: 280-600 kPa

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MUSCA x1

Portable Ventilator

Features

- Portable and easy operation
- Innovative voice-guided direction
- Tidal volume range: 100~1500 ml
- Air Mix option for 60% O_2
- 3 knobs for flexible parameters adjustment
- TFT display of airway pressure and ventilation mode
- 3 ventilation modes. IPPV, Assisted control and Manual control
- Li-ion rechargeable battery with more than 10 hours of working time

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MUSCA x2

Emergency & Transport Ventilator

Features

- Compact design with weight 3.4 kg
- 7"color touch screen with screen lock function
- Airway pressure and EtCO2 real-time waveforms
- Smart CPR mode according to AHA guideline
- I:E ratio range: 1:9 to 9:1; and tidal volume range: 50-2500 ml
- 9 ventilation modes: IPPV, V-AC, V-SIMV, P-AC, P-SIMV, CPAP, PCV, Manual, CPR
- Internal PEEP valve
- 40% or 100% for FiO2
- Rechargeable Li-ion battery with 6 hours working time
- Optional Mainstream EtCO2 analyzer
- Audible and visual alarm for multi-parameters
- IPX4 waterproof

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Intensive Care and Transport Ventilator Solutions

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