Spitalul Clinic Județean de Urgență ARAD
INTRARE Nr. 16363
Data 30.04.20

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=sciaradsecretariat@yahoo.com, SERIALNUMBER=2011042091II1, G=Florina Iustina, SN=Ionescu, CN=Florina Iustina Ionescu
Certificare autenticitate
Computerul meu
2020.05.22 16:39

Gmail spitalul scjuarad.bap@gmail.com

Achizitionare echipamente medicale(3loturi) lotul2 si lotul3

30 aprilie 2020, 10:25

Dan Marin <vanzari2@danson.ro>
Răspunde la: Dan Stroe <office@danson.ro>
Către: scjuarad.bap@gmail.com
Cc: stroe@danson.ro, office@danson.ro

Stimati Colaboratori,

In atasament am postat documentatia necesara participarii noastre, la negocierea directa pentru achizitionarea de echipamente medicale, organizata de D-vstra.

Cu stima,
Dan Stroe,
Director General
s.c. DANSON srl
tel: 021 212 49 09
fax: 0314 055 702
mobil: 0723 566 871.
e-mail: office@danson.ro
str.Aurel Vlaicu, nr.39
ap.3 sect.2 Bucuresti
www.danson.ro

10 atașamente

- **Aviz de functionare DANSON 2019-2024.pdf**
  1507K
- **Certificat CE nr G1 101259 0002.pdf**
  408K
- **Constatator 17.01.2020.pdf**
  3773K
- **Declaratii (5).pdf**
  366K
- **Formular Oferta.pdf**
  82K
- **Manual de operare Axcent LYRA x2.pdf**
  2759K
- **Manual operare Axcent MUSCA x2.pdf**
  3276K
- **Oferta Tehnica Lyra X2 (3).pdf**
  62K
- **Oferta Tehnica Musca X2 (2).pdf**
  64K
- **Prospecte ventilatoare Axcent LYRA si MUSCA.pdf**
  1448K

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ 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

TÜV®

A4 / 07.17

TÜV SÜD ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MINISTERUL JUSTIȚIEI

OFICIUL NAȚIONAL AL REGISTRULUI COMERȚULUI
Oficiul Registrului Comerțului de pe lângă Tribunalul București
Adresa: București, Intrarea Sectorului, nr. 1, sector 3, cod poștal: 030353; Telefon: (+40-21)316.08.28; Fax: (+40-21)316.08.25;
Website: www.onrc.ro; E-mail: orcb@b.onrc.ro;Cod de Identificare Fiscala: 14942091;

BRBAN6RDE

Nr.: 19123/17.01.2020

CERTIFICAT CONSTATATOR

În conformitate cu prevederile Legii nr. 26/1990 privind registrul comerțului, republicată, cu modificările și completările ulterioare și ca urmare a cererii dumneavoastră înregistrată sub nr. 19123 din 17.01.2020, Oficiul Național al Registrului Comerțului / Oficiul Registrului Comerțului de pe lângă Tribunalul București certifică informațiile referitoare la

DANSON SRL

INFORMAȚII DE IDENTIFICARE

Număr de ordine în Registrul Comerțului: J40/23606/1993, atribuit în data de 11.10.1993
Identificator Unic la Nivel European (EUID): ROONRC.J40/23606/1993
Cod unic de înregistrare: 4781338
Certificat de înregistrare: B2611091, emis pe data de 07.06.2012 si eliberat la data 08.06.2012
Adresă sediu social: București Sectorul 2, Bulevardul DACIA, Nr. 81, Etaj PARTER, Ap. 1
Contacte sediu social: Fax 012116515, Telex 0, telefon: 012124909, 0723566871
Contacte firmă: Fax 012116515, Telex 0, telefon: 012124909, 0723566871
Actul de înmatriculare și autorizare: Sentință civilă / Hotărâre judecătorească 4073/15.09.93,JUD. SECT. 2
Stare firmă: funcțiune
Forma de organizare : societate cu raspundere limitata
Data ultimei înregistrări în registrul comerțului: 10.09.2019
Durată: nelimitată;

SEDIU SOCIAL

Act sediu: Contract de comodat, nr. 1 din data 29.05.2012
Data de început a valabilității pentru dovada de sediu: 29.05.2012.
Data expirării dovezii de sediu: 28.05.2022.
Durata sediului: 9 ani 11 luni 29 zile.

CAPITAL SOCIAL

Capital social subscris: 451000 LEI , integral vărsat
Număr părți sociale: 45100
Valoarea unei părți sociale: 10 LEI

ASOCIAȚI PERSOANE JURIDICE

Nu există înregistrări.

Redactat N.A.G. / listat 17.01.2020 : 13:24:43

ASOCIAȚI PERSOANE FIZICE
STROE MARIAN
Calitate: asociat
Cetățenie: română
Stare civilă: casatorit
Data şi locul naşterii: 02.12.1946, MOSOAIA, ARGES
Sex: masculin
Aport la capital: 450800 LEI
Aport vărsat total: 450800 LEI
Aport vărsat în LEI : 450800 LEI
Număr parți sociale: 45080
Cota de participare la beneficii şi pierderi: 99.956% / 99.956%

STROE DAN IONUT
Calitate: asociat
Cetățenie: română
Stare civilă: necasatorit
Data şi locul naşterii: 07.06.1980, BUCURESTI
Sex: masculin
Aport la capital: 100 LEI
Aport vărsat total: 100 LEI
Aport vărsat în LEI : 100 LEI
Număr parți sociale: 10
Cota de participare la beneficii şi pierderi: 0.022% / 0.022%

STROE MICHAELA IULIA
Calitate: asociat
Cetățenie: română
Stare civilă: casatorit
Data şi locul naşterii: 11.01.1947, ORSOVA, MEHEDINTI
Sex: feminin
Aport la capital: 100 LEI
Aport vărsat total: 100 LEI
Aport vărsat în LEI : 100 LEI
Număr parți sociale: 10
Cota de participare la beneficii şi pierderi: 0.022% / 0.022%

REPREZENTANT acționar/asociat/membru (PERSOANĂ JURIDICĂ)
Nu există înregistrări.

ASOCIAT, reprezentant al deținatorilor în comun de părți sociale (PERSOANĂ FIZICĂ)
Nu există înregistrări.

Persoane împuternicite (PERSOANE FIZICE)
STROE MARIAN
Calitate: administrator
Funcție: nespecificata
Cetățenie: română
Sex: masculin
Data şi locul naşterii: 02.12.1946, MOSOAIA, ARGES

BRBAN6RDE

Puteri: DEPLINE
Data numirii în funcție: 05.10.1993
Durată mandat: nelimitată

Persoane împuternicite (PERSOANE JURIDICE)
Nu există înregistrări.

Administratori judiciari / Lichidatori judiciari/ Lichidatori (PERSOANE JURIDICE)
Nu există înregistrări.

CURATOR / CURATOR SPECIAL
Nu există înregistrări.

Cenzori / Auditori PERSOANE JURIDICE
Nu există înregistrări.

Cenzori / Auditori PERSOANE FIZICE
Nu există înregistrări.

Activitatea principală
Domeniul de activitate principal: conform codificarii (Ordin 337/2007) Rev. Caen (2)
4646 - Comerț cu ridicata al produselor farmaceutice

FILIALE / SUCURSALE / SUBUNITĂȚI
Nu există înregistrări.

SEDII SECUNDARE / PUNCTE DE LUCRU
Denumire: PUNCT DE LUCRU
Adresă: Loc. Sinaia, Oraş Sinaia, Str. AVRAM IANCU, Nr. 2, Bloc 4, Etaj 8, Ap. 35, Judet Prahova
Act sediu: Contract de comodat, nr. 697 din data 08.11.2004
Data de început a valabilității pentru dovada de sediu: 08.11.2004.
Durata sediului: 99 ani.

Denumire: PUNCT DE LUCRU - BIROURI
Adresă: Bucureşti Sectorul 2, Str. AUREL VLAICU, Nr. 39, Ap. 3
Act sediu: Contract de închiriere, nr. 225273 din data 08.06.2015
Data de început a valabilității pentru dovada de sediu: 01.07.2015.
Data expirării dovezii de sediu: 30.06.2020.
Durata sediului: 4 ani 11 luni 29 zile.

SEDII SI/SAU ACTIVITATI AUTORIZATE CONFORM ART. 15 DIN L359/2004

Sediul social din:Bucureşti Sectorul 2, Bulevardul DACIA, Nr. 81, Etaj PARTER, Ap. 1
Tip sediu: principal
Tip model declarație: model 1 nr. 651789 din 01.06.2012
Nu se desfășoară activitățile prevăzute în actul constitutiv sau modificator
Data certificatului constatator: 07.06.2012

Denumire: PUNCT DE LUCRU
Sediul secundar din:Loc. Sinaia, Oraş Sinaia, Str. AVRAM IANCU, Nr. 2, Bloc 4, Etaj 8, Ap. 35, Judet Prahova
Tip sediu: sediu secundar
Tip model declaraţie: model 3 nr. 103555 din 21.03.2014
Activităţi la sediu:
4646 - Comerţ cu ridicata al produselor farmaceutice
3314 - Repararea echipamentelor electrice
3313 - Repararea echipamentelor electronice şi optice
4619 - Intermedieri în comerţul cu produse diverse
7022 - Activităţi de consultanţă pentru afaceri şi management
Data certificatului constatator: 26.03.2014

Denumire: PUNCT DE LUCRU - BIROURI
Sediul secundar din:Bucureşti Sectorul 2, Str. AUREL VLAICU, Nr. 39, Ap. 3
Tip sediu: sediu secundar
Tip model declaraţie: model 3 nr. 103555 din 21.03.2014
Activităţi la sediu:
7022 - Activităţi de consultanţă pentru afaceri şi management
3314 - Repararea echipamentelor electrice
3313 - Repararea echipamentelor electronice şi optice
4774 - Comerţ cu amănuntul al articolelor medicale şi ortopedice, în magazine specializate
4646 - Comerţ cu ridicata al produselor farmaceutice
2651 - Fabricarea de instrumente şi dispozitive pentru măsură, verificare, control, navigaţie
3250 - Fabricarea de dispozitive, aparate şi instrumente medicale şi stomatologice
2660 - Fabricarea de echipamente pentru radiologie, electrodiagnostic şi electroterapie
Data certificatului constatator: 26.03.2014

CONCORDAT PREVENTIV
Nu există înregistrări.

FAPTE AFLATE SUB INCIDENTA ART 21. LIT. e-h) din L26/1990
- Urmărire penală:
Nu există înregistrări.

- Dosar penal - trimitere în judecată:
Nu există înregistrări.

- Condamnare penală a firmei:
Nu există înregistrări.

- Dizolvare firmă:
Nu există înregistrări.

- Lichidare firmă:
Nu există înregistrări.

- Insolvenţă:

BRBAN6RDE

Nu există înregistrări.

SITUAȚIA FINANCIARĂ PE ANUL 2018
22. PROFITUL SAU PIERDEREA NET(Ă) A EXERCIȚIULUI FINANCIAR:- Profit (rd. 64 - 65 - 66 - 67 - 68): 84928 LEI
22. PROFITUL SAU PIERDEREA NET(Ă) A EXERCIȚIULUI FINANCIAR:- Pierdere (rd. 65 + 66 + 67 + 68 - 64): 0 LEI
18. PROFITUL SAU PIERDEREA BRUT(Ă):- Pierdere (rd. 63 - 62): 0 LEI
18. PROFITUL SAU PIERDEREA BRUT(Ă):- Profit (rd. 62 - 63): 106598 LEI
Numar mediu de salariati: 7
Impozite, contributii si taxe neplatite la termenul stabilit la bugetul de stat, din care:: 0 LEI
1. Cifra de afaceri netă (rd. 02+03-04+05+06): 5229443 LEI
ACTIVE IMOBILIZATE - TOTAL (rd. 01 + 02 + 03): 2502907 LEI

Informațiile sunt eliberate din registrul central computerizat al comerțului, ținut de Oficiul Național al Registrului Comerțului și au la bază comunicarea înregistrărilor efectuate în registrul comerțului ținut de către oficiile registrului comerțului de pe lângă tribunale până la data de 17.01.2020

S-a eliberat prezentul certificat constatator solicitantului STROE DAN IONUT , fiindu-i necesar la Licitație.

DIRECTOR

ȘTEFANIA-CARMEN CHIȚU

Potrivit prevederilor art. 22 alin. (1) și alin. (2) din Legea nr. 26/1990 privind registrul comerțului, republicată, cu modificările și completările ulterioare, profesionistul are obligația să solicite înregistrarea în registrul comerțului a mențiunilor prevăzute de lege, în cel mult 15 zile de la data actelor și faptelor supuse obligației de înregistrare. Înregistrarea mențiunilor se poate face și la cererea persoanelor interesate, în termen de cel mult 30 de zile de la data când au cunoscut actul sau faptul supus înregistrării.
În cazul persoanelor împuternicite al căror mandat a expirat, însă profesionistul nu a procedat la înregistrarea în registrul comerțului a mențiunilor corespunzătoare, conform celor de mai sus, acesta va figura în continuare înregistrat în registrul comerțului computerizat, cu calitatea respectivă și cu durata mandatului expirată.

Prezentul document conține date cu caracter personal a căror prelucrare intră sub incidența prevederilor Regulamentului (UE) nr. 679/2016 privind protecția persoanelor fizice în ceea ce privește prelucrarea datelor cu caracter personal și privind libera circulație a acestor date și de abrogare a Directivei 95/46/CE.
Informațiile cu privire la datele cu caracter personal furnizate prin prezentul document pot fi utilizate exclusiv în scopul pentru care au fost solicitate.

Contrafacerea prezentului document constituie infracțiune și se pedepsește conform legii.

S C DANSON srl

Formular nr. **1**

DECLARAȚIE PRIVIND RESPECTAREA OBLIGATIILOR REFERITOARE LA CONDIȚIILE DE MUNCĂ ȘI DE PROTECȚIA 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 30.04.2020

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

.....

S C DANSON srl **Formularul** nr. 7

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

Subsemnatul Dan Ionut S...

S C DANSON srl.

Formularul nr. 8

Declaraţie privind neîncadrarea în situaţiile prevăzute la art. 167 din Legea 98/2016 privind achizitiile publice

Subsemnata **Dan Ionut Stroe** reprezentanta al **SC DANSON SRL,** în calitate de ofertant, la procedura Negociere fara publicare a unui anunt de participare pentru atribuirea contractului avand ca obiect „Achizitionare echipamente de protectie 1o0 loturi", organizata de Spitalul Clinic Judetean de Urgenta Arad, in data de 07.04.2020, declar pe propria răspundere că nu sunt în situaţiile prevăzute în art. 167 din Legea 98/2016 privind achiziţiile publice.

ART. 167

(1) Autoritatea contractantă exclude din procedura de atribuire a contractului de achiziţie publică/acordului-cadru orice operator economic care se află în oricare dintre următoarele situaţii:

a) a încălcat obligaţiile stabilite potrivit art. 51, iar autoritatea contractantă poate demonstra acest lucru prin orice mijloc de probă adecvat, cum ar fi decizii ale autorităţilor competente prin care se constată încălcarea acestor obligaţii;

b) se află în procedura insolvenţei sau în lichidare, în supraveghere judiciară sau în încetarea activităţii;

c) a comis o abatere profesională gravă care îi pune în discuţie integritatea, iar autoritatea contractantă poate demonstra acest lucru prin orice mijloc de probă adecvat, cum ar fi o decizie a unei instanţe judecătoreşti sau a unei autorităţi administrative;

d) autoritatea contractantă are suficiente indicii rezonabile/informaţii concrete pentru a considera că operatorul economic a încheiat cu alţi operatori economici acorduri care vizează denaturarea concurenţei în cadrul sau în legătură cu procedura în cauză;

e) se află într-o situaţie de conflict de interese în cadrul sau în legătură cu procedura în cauză, iar această situaţie nu poate fi remediată în mod efectiv prin alte măsuri mai puţin severe;

f) participarea anterioară a operatorului economic la pregătirea procedurii de atribuire a condus la o distorsionare a concurenţei, iar această situaţie nu poate fi remediată prin alte măsuri mai puţin severe;

g) operatorul economic şi-a încălcat în mod grav sau repetat obligaţiile principale ce-i reveneau în cadrul unui contract de achiziţii publice, al unui contract de achiziţii sectoriale sau al unui contract de concesiune încheiate anterior, iar aceste încălcări au dus la încetarea anticipată a respectivului contract, plata de daune-interese sau alte sancţiuni comparabile;

h) operatorul economic s-a făcut vinovat de declaraţii false în conţinutul informaţiilor transmise la solicitarea autorităţii contractante în scopul verificării absenţei motivelor de excludere sau al îndeplinirii criteriilor de calificare şi selecţie, nu a prezentat aceste informaţii sau nu este în măsură să prezinte documentele justificative solicitate;

i) operatorul economic a încercat să influenţeze în mod nelegal procesul decizional al autorităţii contractante, să obţină informaţii confidenţiale care i-ar putea conferi avantaje nejustificate în cadrul procedurii de atribuire sau a furnizat din neglijenţă informaţii eronate care pot avea o influenţă semnificativă asupra deciziilor autorităţii contractante privind excluderea din procedura de atribuire a respectivului operator economic, selectarea acestuia sau atribuirea contractului de achiziţie publică/acordului-cadru către respectivul operator economic.

(2) Prin excepţie de la dispoziţiile alin. (1) lit. b), autoritatea contractantă nu exclude din procedura

(3) În sensul dispoziţiilor alin. (1) lit. c), prin abatere profesională gravă se înţelege orice abatere comisă de operatorul economic care afectează reputaţia profesională a acestuia, cum ar fi încălcări ale regulilor de concurenţă de tip cartel care vizează trucarea licitaţiilor sau încălcări ale drepturilor de proprietate intelectuală, săvârşită cu intenţie sau din culpă gravă.

(4) Dispoziţiile alin. (1) lit. c) sunt aplicabile şi în situaţia în care operatorul economic sau una dintre persoanele prevăzute la art. 164 alin. (2) este supusă unei proceduri judiciare de investigaţie în legătură cu săvârşirea uneia/unora dintre faptele prevăzute la art. 164 alin. (1).

(5) În sensul dispoziţiilor alin. (1) lit. d) se consideră că autoritatea contractantă are suficiente indicii plauzibile pentru a considera că operatorul economic a încheiat cu alţi operatori economici acorduri care vizează denaturarea concurenţei în cadrul sau în legătură cu procedura în cauză în următoarele situaţii, reglementate cu titlu exemplificativ:

a) ofertele sau solicitările de participare transmise de 2 sau mai mulţi operatori economici participanţi la procedura de atribuire prezintă asemănări semnificative din punct de vedere al conţinutului documentelor nestandardizate potrivit documentaţiei de atribuire;

b) în cadrul organelor de conducere a 2 sau mai multor operatori economici participanţi la procedura de atribuire se regăsesc aceleaşi persoane sau persoane care sunt soţ/soţie, rudă sau afin până la gradul al doilea inclusiv ori care au interese comune de natură personală, financiară sau economică sau de orice altă natură;

c) un ofertant/candidat a depus două sau mai multe oferte/solicitări de participare, atât individual cât şi în comun cu alţi operatori economici sau doar în comun cu alţi operatori economici;

d) un ofertant/candidat a depus ofertă/solicitare de participare individuală/în comun cu alţi operatori economici şi este nominalizat ca subcontractant în cadrul unei alte oferte/solicitări de participare.

(6) Înainte de excluderea unui operator economic în temeiul alin. (1) lit. d), autoritatea contractantă solicită în scris Consiliului Concurenţei punctul de vedere cu privire la indiciile identificate care vizează denaturarea concurenţei în cadrul sau în legătură cu procedura de atribuire în cauză, pe care acesta îl va înainta în termen de maximum 15 zile.

(7) Autoritatea contractantă are obligaţia furnizării tuturor informaţiilor solicitate de Consiliul Concurenţei, în vederea formulării punctului de vedere, conform dispoziţiilor alin. (6).

(8) În sensul dispoziţiilor alin. (1) lit. g) se consideră încălcări grave ale obligaţiilor contractuale, cu titlu exemplificativ, neexecutarea contractului, livrarea/prestarea/executarea unor produse/servicii/lucrări care prezintă neconformităţi majore care le fac improprii utilizării conform destinaţiei prevăzute în contract.

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

Înţeleg că în cazul în care această declaraţie nu este conformă cu realitatea sunt posibil de încălcarea prevederilor legislaţiei penale privind falsul în declaraţii.

Data completării 30.04.2020

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

.....

S C DANSON srl

Formular 9

DECLARAȚIE

privind neîncadrarea în situațiile prevăzute la art. 164 din Legea 98/2016

privind achizitiile publice

Subsemnatul Dan Ionut Stroe reprezentanta al **S C DANSON SRL,** în calitate de ofertant declar pe propria răspundere, sub sancțiunea excluderii din procedură și a sancțiunilor aplicate faptei de fals în acte publice, că **nu mă aflu în situațiile prevăzute la art. 164 din Legea 98/2016** privind atribuirea contractelor de achiziție publică, respectiv nu am fost condamnat prin hotărâre definitivă a unei instanțe judecătorești, pentru comiterea uneia dintre următoarele infracțiuni:

a)constituirea unui grup infracțional organizat, prevăzută de art. 367 din Legea nr. 286/2009 privind Codul penal, cu modificările și completările ulterioare, sau de dispozițiile corespunzătoare ale legislației penale a statului în care respectivul operator economic a fost condamnat;

b)**infracțiuni de corupție**, prevăzute de art. 289-294 din Legea nr. 286/2009, cu modificările și completările ulterioare, și infracțiuni asimilate infracțiunilor de corupție prevăzute de art. 10-13 din Legea nr. 78/2000 pentru prevenirea, descoperirea și sancționarea faptelor de corupție, cu modificările și completările ulterioare, sau de dispozițiile corespunzătoare ale legislației penale a statului în care respectivul operator economic a fost condamnat;

c)infracțiuni împotriva intereselor financiare ale Uniunii Europene, prevăzute de art. 181 -185 din Legea nr. 78/2000, cu modificările și completările ulterioare, sau de dispozițiile corespunzătoare ale legislației penale a statului în care respectivul operator economic a fost condamnat;

d)acte de terorism, prevăzute de art. 32-35 și art. 37-38 din Legea nr. 535/2004 privind prevenirea și combaterea terorismului, cu modificările și completările ulterioare, sau de dispozițiile corespunzătoare ale legislației penale a statului în care respectivul operator economic a fost condamnat;

e)spălarea banilor, prevăzută de art. 29 din Legea nr. 656/2002 pentru prevenirea și sancționarea spălării banilor, precum și pentru instituirea unor măsuri de prevenire și combatere a finanțării terorismului, republicată, cu modificările ulterioare, sau finanțarea terorismului, prevăzută de art. 36 din Legea nr. 535/2004, cu modificările și completările ulterioare, sau de dispozițiile corespunzătoare ale legislației penale a statului în care respectivul operator economic a fost condamnat;

f)traficul și exploatarea persoanelor vulnerabile, prevăzute de art. 209-217 din Legea nr. 286/2009, cu modificările și completările ulterioare, sau de dispozițiile corespunzătoare ale legislației penale a statului în care respectivul operator economic a fost condamnat;

g)fraudă, în sensul articolului 1 din Convenția privind protejarea intereselor financiare ale Comunităților Europene din 27 noiembrie 1995.

De asemenea, declar pe propria răspundere, sub sancțiunea excluderii din procedură și a sancțiunilor aplicate faptei de fals în acte publice, că nici un membru al organului de administrare, de conducere sau de supraveghere al societății sau cu putere de reprezentare, de decizie sau de control în cadrul acesteia nu face obiectul excluderii așa cum este acesta definit la art. 164, alin (1) din Legea 98/2016.

Subsemnatul Dan Ionut Stroe, declar că informațiile furnizate sunt complete și corecte în fiecare detaliu și înțeleg că autoritatea contractantă are dreptul de a solicita, în scopul verificării și confirmării declarațiilor orice documente doveditoare de care dispunem.

Înteleg că în cazul în care această declarație nu este conformă cu realitatea sunt pasibil de încălcarea prevederilor legislației penale privind falsul în declarații.

Data completării 30.04.2020

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

.....

S C DANSON srl

OFERTA TEHNICA

Denumire utilaj : Aparat de ventilatie mecanica

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

SPECIFICATII	CONFORMITATE		
	Da	Nu	Document / pagina
Alimentare cu oxigen conector autocuplant	X		Conf. Prospect pag.13
Alimentare la 220V 50Hz	X		Conf. Prospect pag.11
Dimensiuni : 664x600x1520mm cu carucior(troler)	X		Conf. Prospect pag.8: 664x600x1520mm
Greutate : 33 kg cu carucior	X		Conf. Prospect pag.8 33 kg cu troller
Afisaj color tactil	X		Conf. Prospect pag.7
Tipuri de pacienti : adult, copil, neonatal	X		Conf. Prospect pag.8
Moduri de ventilatie invaziva :VCV, PCV, VSIMV, PSIMV,CPAP/PSV, PRVC, V+SIMV, BPAP, APRV.	X		Conf. Prospect pag.8
Moduri de ventilatie noninvaziva : CPAP, PCV, PPS, S/T, VS.	X		Conf. Prospect pag.8
Oxigen conc : 21%-100%	X		Conf. Prospect pag.8
Volum tidal adult, pediatric, nounascut	X		Conf. Prospect pag.8, adult 100-2000 ml, pediatric 20-300ml,neonat 20-300ml
Frecventa resp 1-80rpm	X		Conf. Prospect pag.8, adult 1-80rpm
Frecventa resp nounascut 1-150rpm	X		Conf. Prospect pag.8, neonat 1-150
PEEP 1-45cmH20 sau oprit	X		Conf. Prospect pag.8, 1-45cmH20
Suspin interval 20s-180min	X		Conf. Prospect pag.9, 20s-180min
Alarme:	X		
Volum Tidal	X		Conf. Prospect pag.11
Volum pe minut	X		Conf. Prospect pag.11
Presiune caii respiratorii	X		Conf. Prospect pag.11
Apnee	X		Conf. Prospect pag.11
Frecventa	X		Conf. Prospect pag.11
Concentratie oxigen	X		Conf. Prospect pag.11
Baterie interna LI-ION, 11,25VDC,6400mAh	X		Conf. Prospect pag.11
Autonomie 3 ore de functionare	X		Conf. Prospect pag.11
Garantie 24 luni	X		Se asigura garantie de 24 **luni** de la data punerii in functiune
Instalarea , punerea in functiune precum si instruirea personalului benficiarului, sunt operatiuni ce cad in sarcina furnizorului si sunt incluse in pret.			Se asigura instalarea punere in functine si instriurea personalului beneficiarului

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

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 24 de luni	X		Se asigura garantie de **24 de luni** de la data punerii in functiune

Ofertant:
DANSON srl
Director General
Dan Stroe,

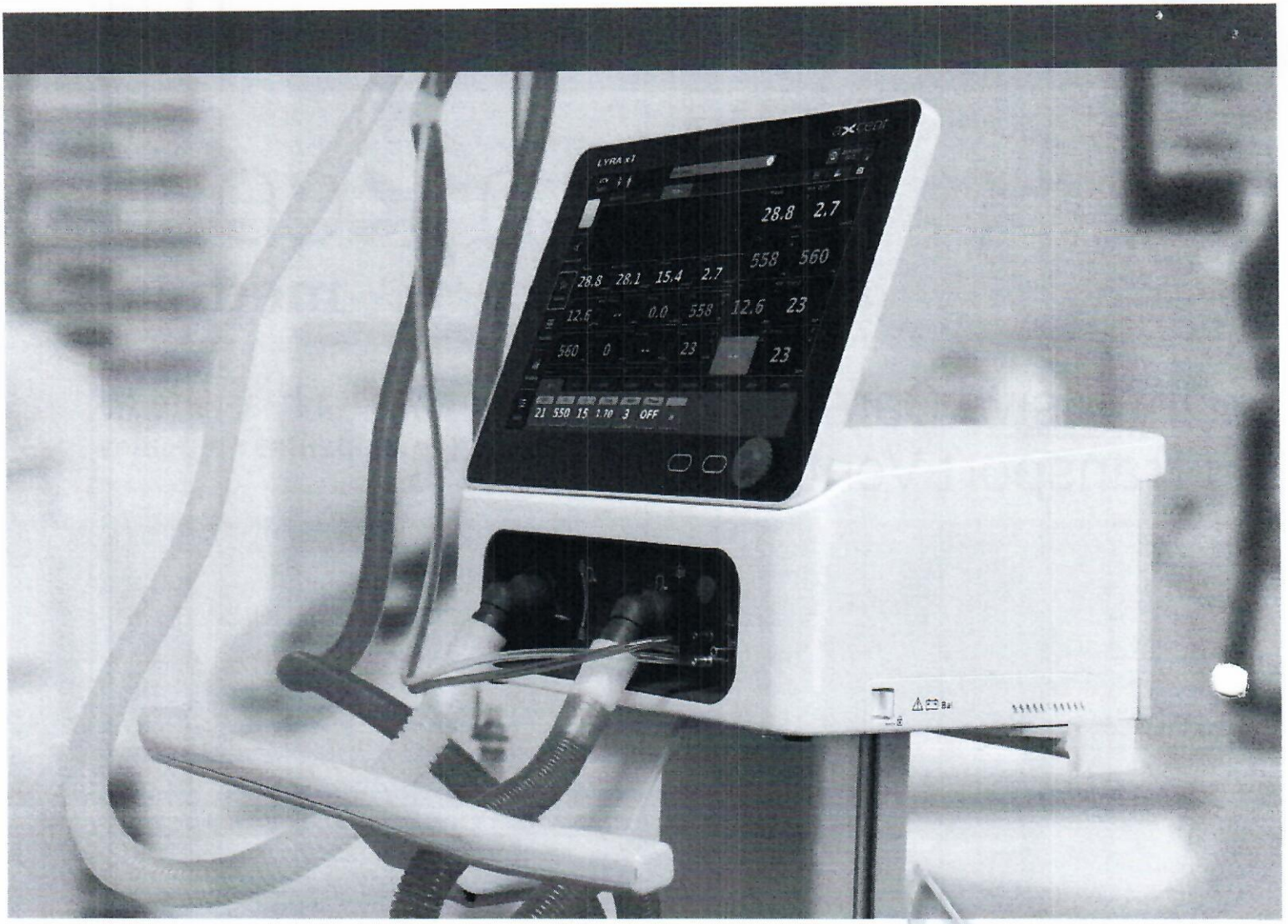
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Intensive Care and Transport Ventilator Solutions



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

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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	Continuous Flow (O Therapy)
MV spn	Ri	

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

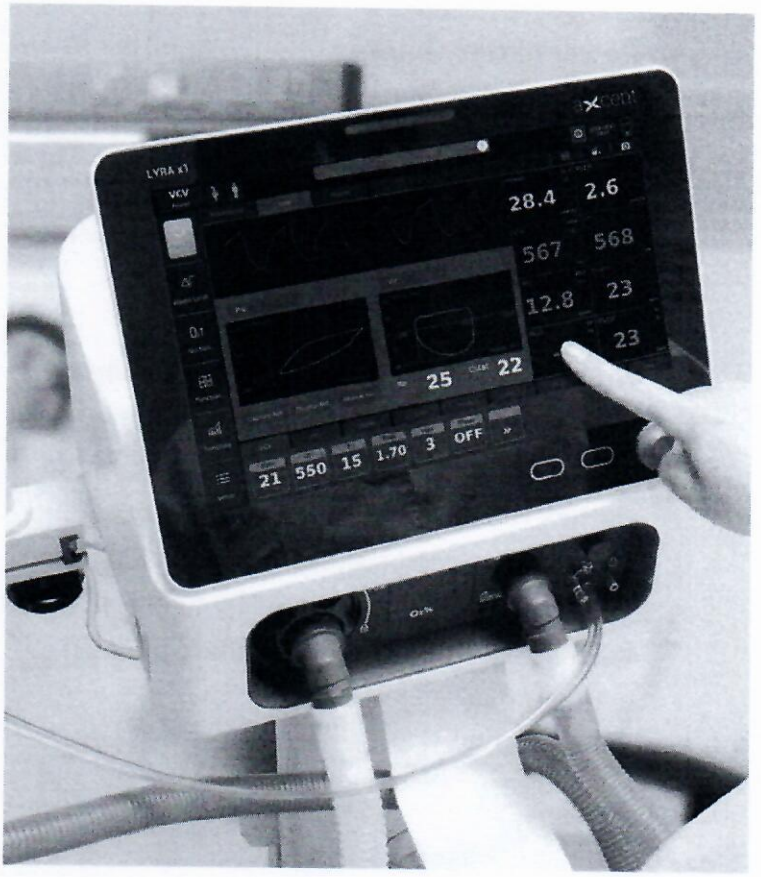
Apnea alarm time: 5-60 s

Trend

Type: Tabular, Graphic

Length: 72 hours

Content: Monitor Parameters, Setting Parameters (Setting Ventilation mode and Parameters)



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LYRA x1

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

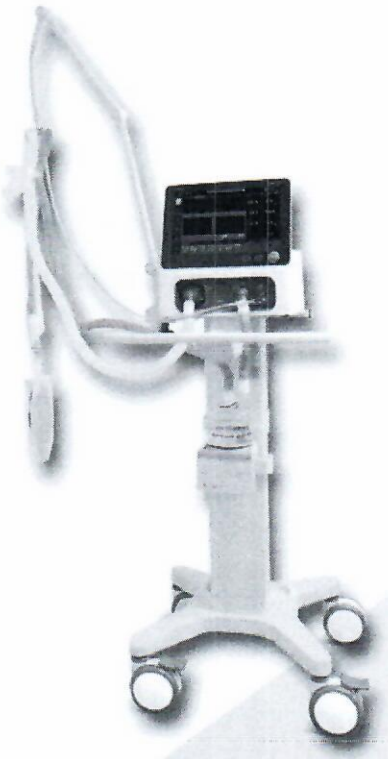
Temperature: 5-40 °C (operating); -20 to 60 °C (storage and transport, O_2sensor: -20 to 50 °C)
Relative Humidity: 10-95% (operating); 10-95% (storage and transport)
Barometric Pressure: 62-106 kPa (operating); 50-106 kPa (storage and transport)

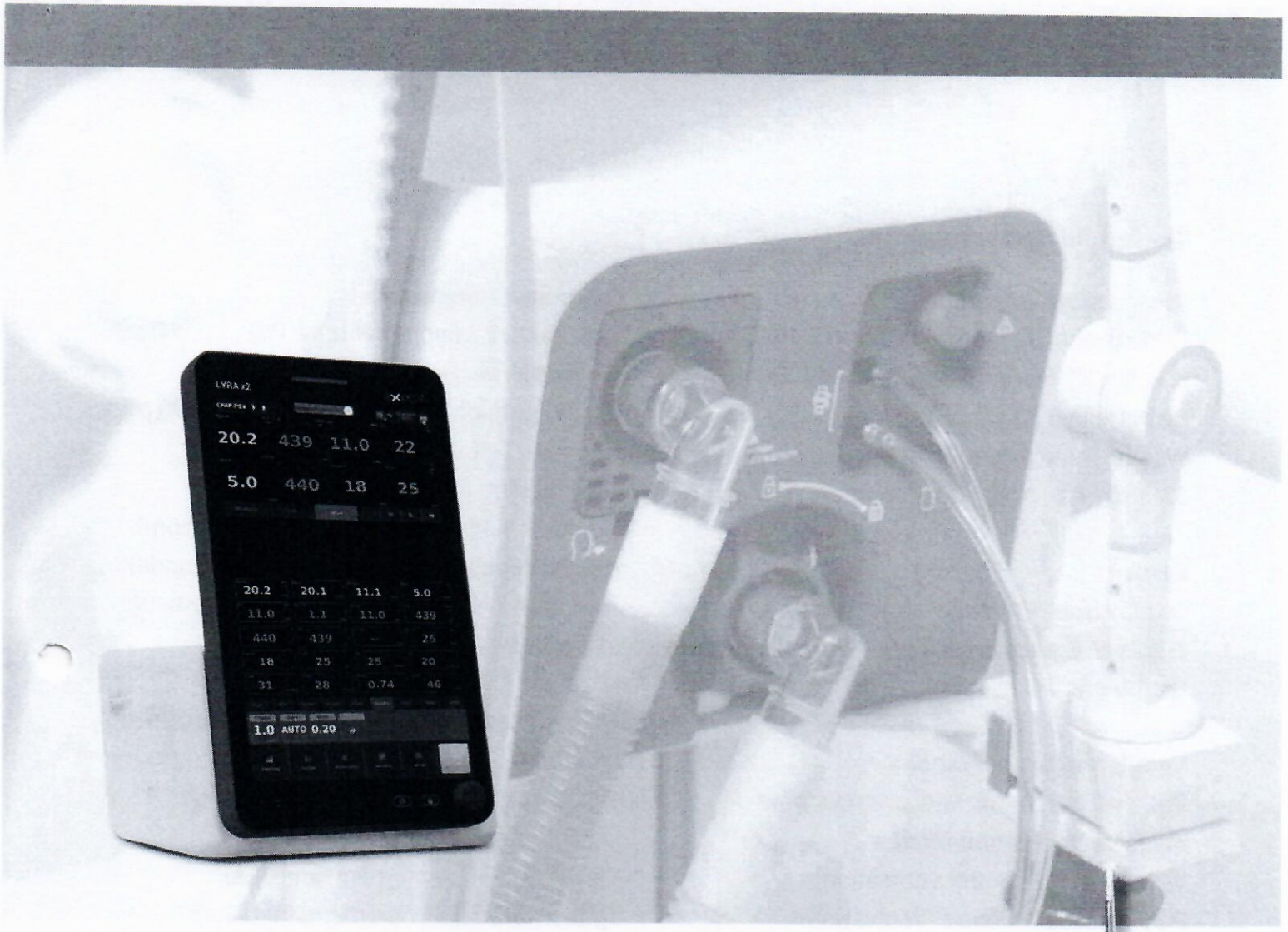
Power Battery Backup

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.



axcent **medical**

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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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)
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%
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
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)

O_2 Therapy

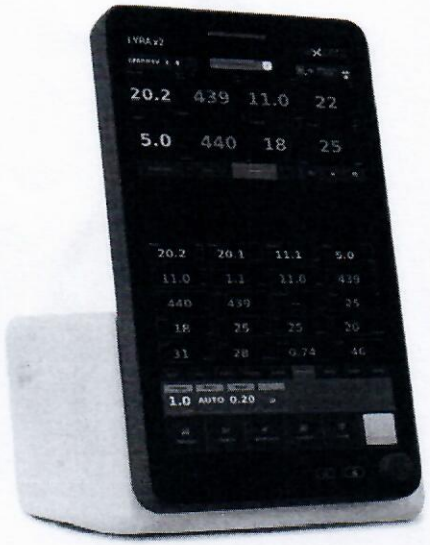
Controlled Parameters
O_2%: 21-100% (increments of 1%)
Flow: 4-60 L/min
Controlled Accuracy
O_2%: ±(3 vol.% +1% of setting)
Flow: ±(2 L/min +10% of setting) (BTPS)

Environmental specifications

Temperature: 5-40°C (operating); -20 to 60 °C (storage and transport, O_2 sensor: -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 battery in standard working condition)



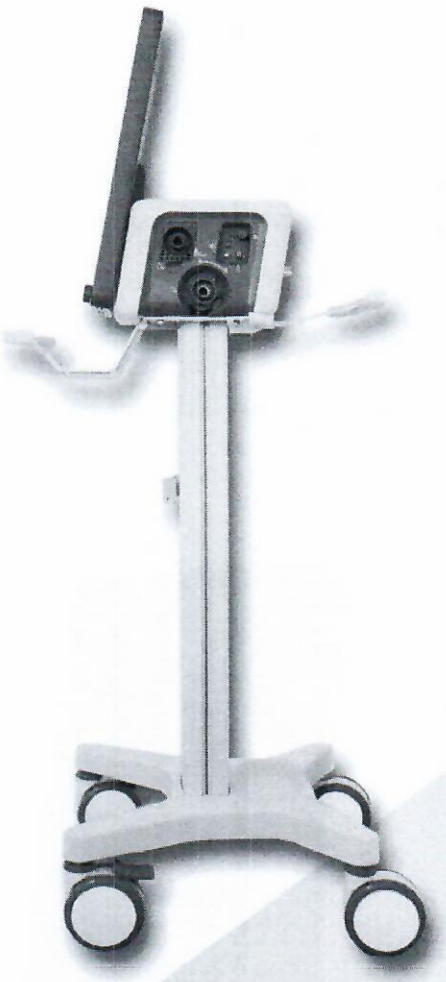
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Technical Specifications

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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MUSCA x2 | Transport Ventilator

User Manual



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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.

Intellectual Property Right

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Statement

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aXcent reserves the right to change related technology without prior notice.

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
	Battery level indication		Adapter off
	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

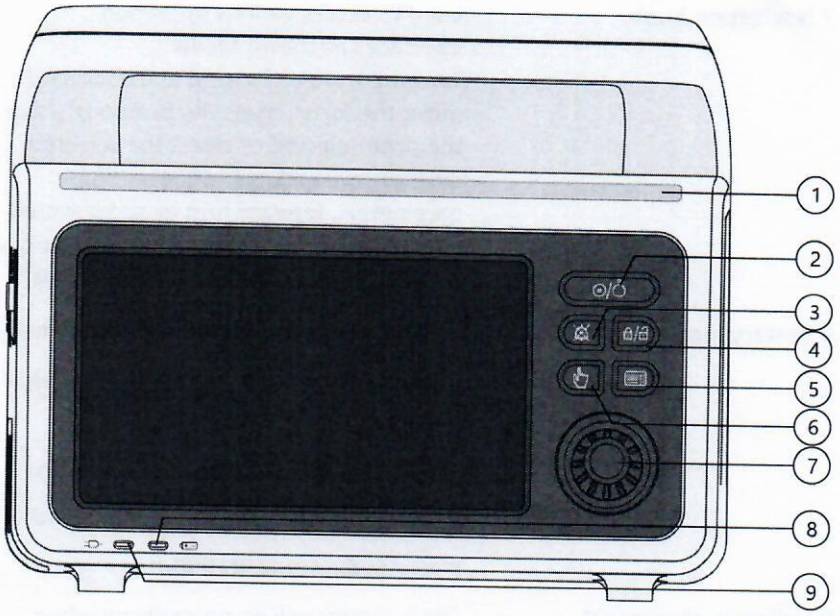


FIGURE 1 Main Unit (Front View)

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

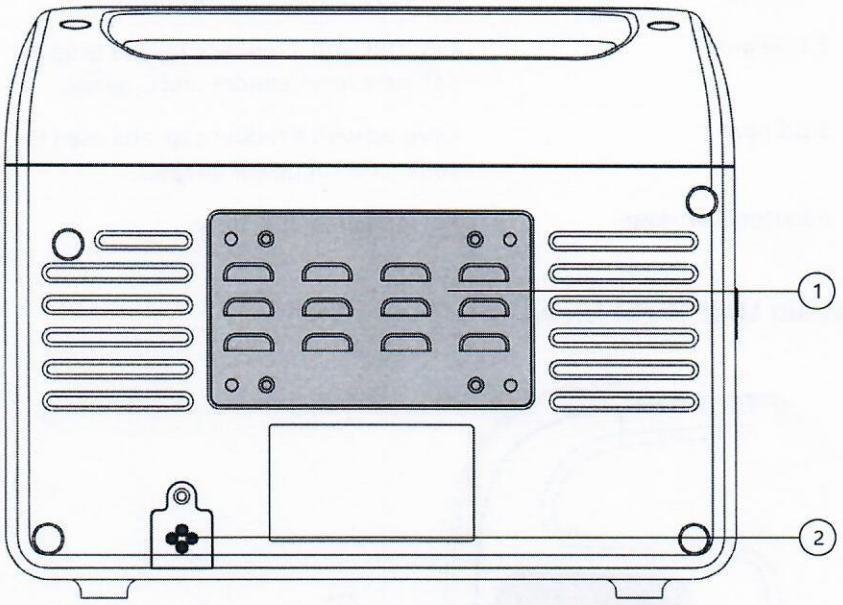


FIGURE 2 Main Unit (Rear View)

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

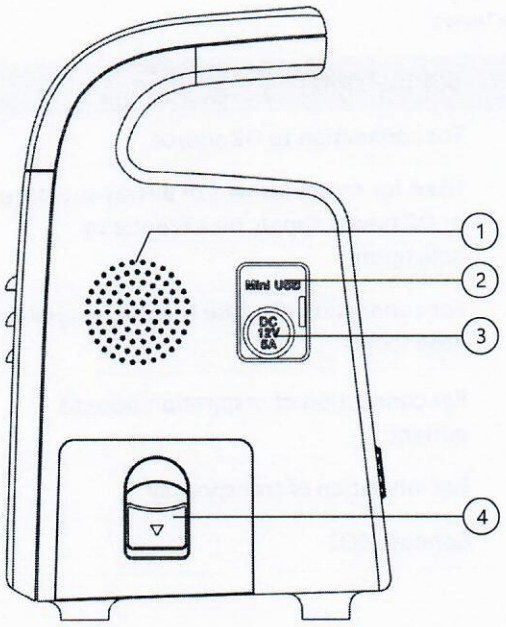


FIGURE 3 Main Unit (Left View)

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

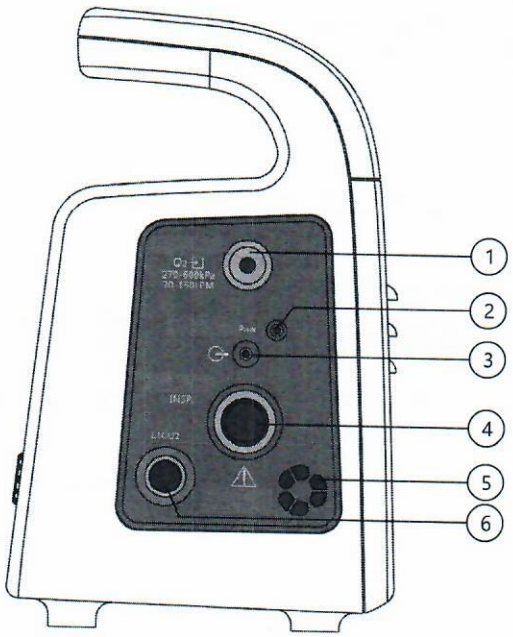


FIGURE 4 Main Unit (Right View)

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

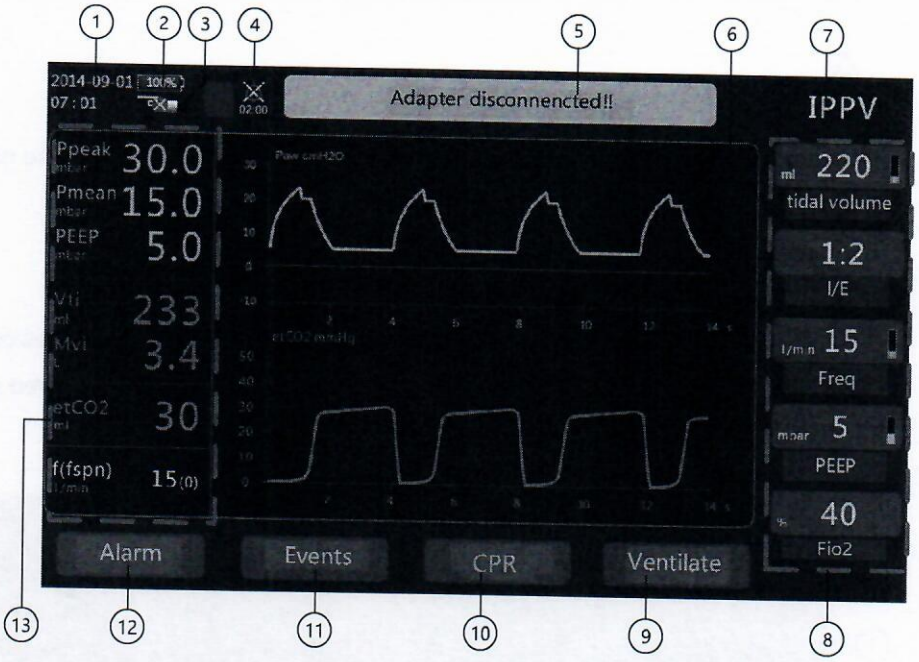


FIGURE 5 Main interface

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).

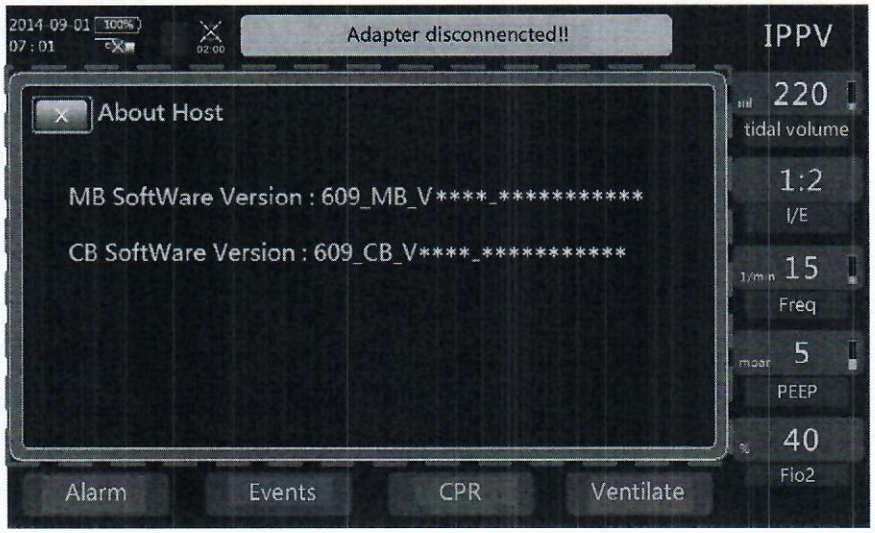


FIGURE 12 About Host

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).

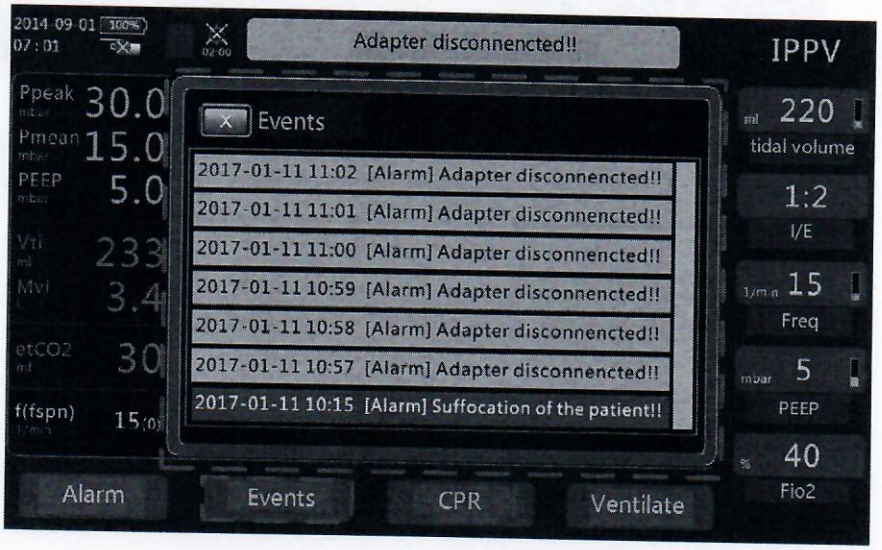


FIGURE 14 Events

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).

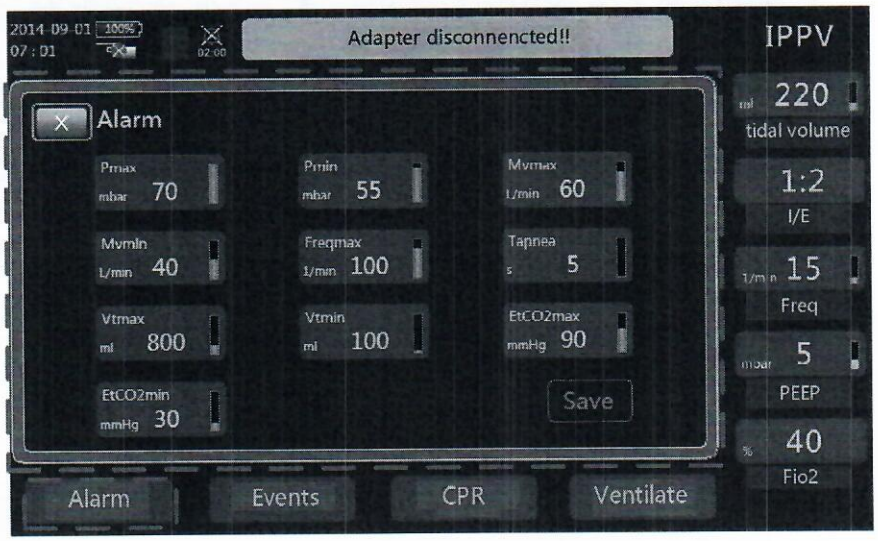


FIGURE 15 Alarm

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.

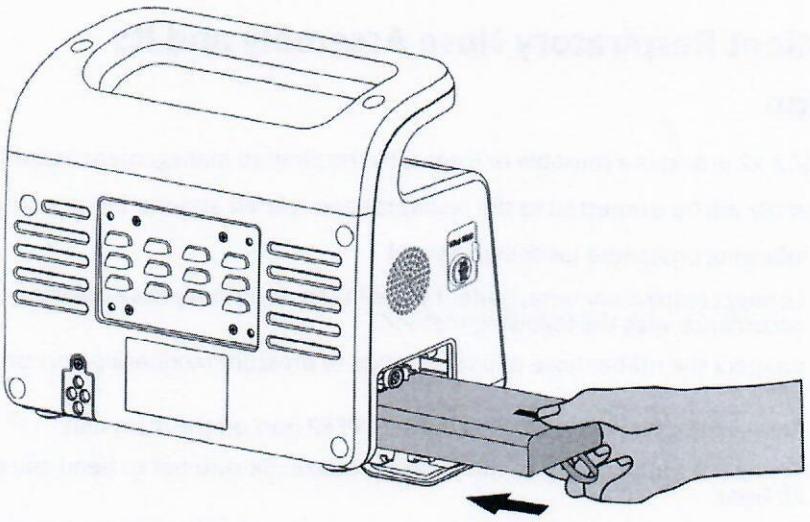


FIGURE 16 Install the battery

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.

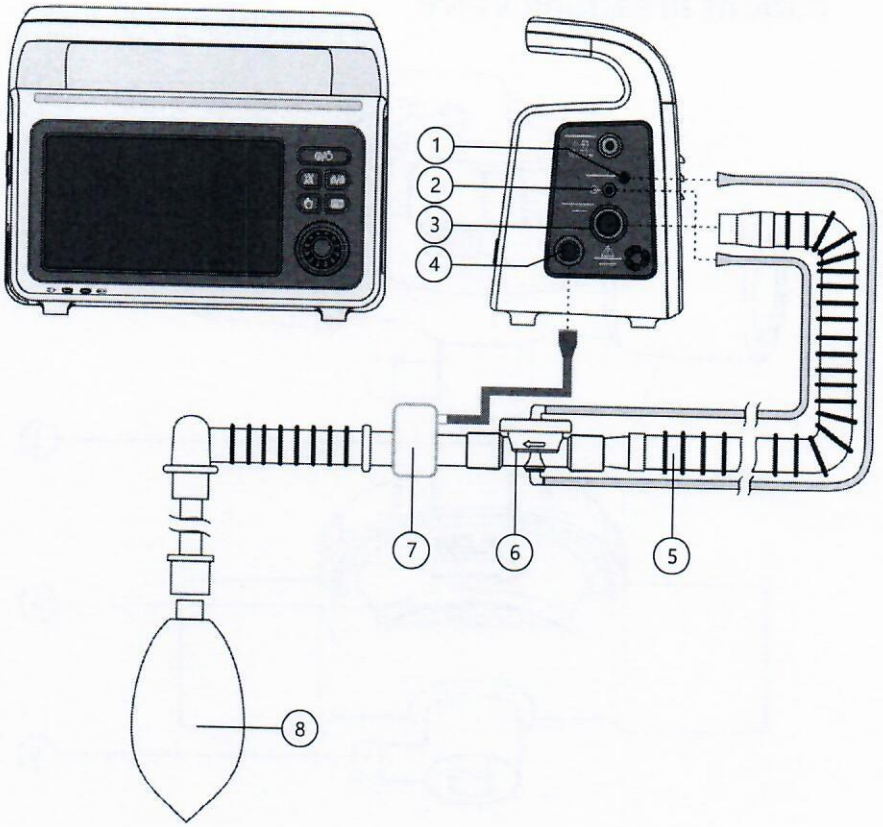


FIGURE 17 Accessories Connection Diagram

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

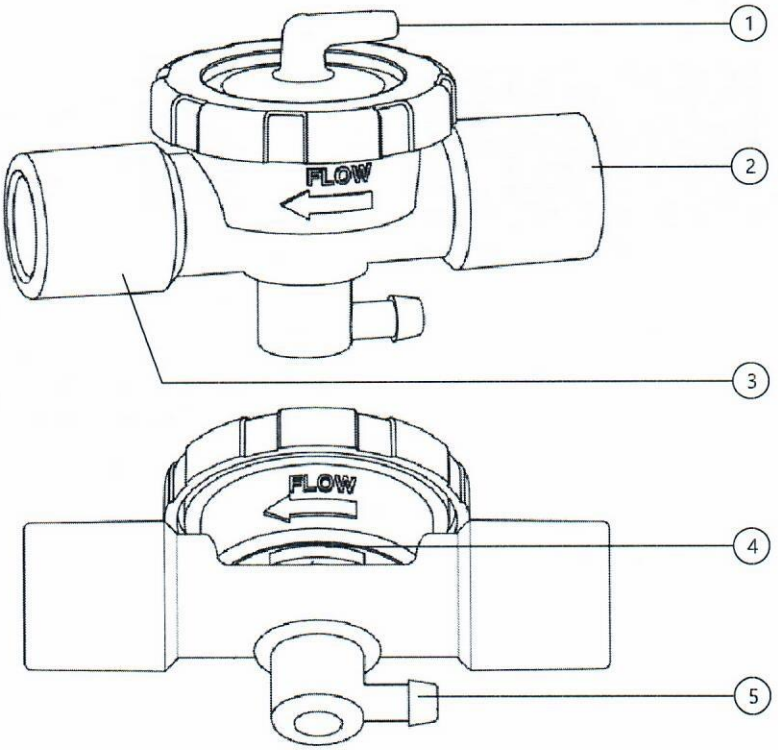


FIGURE 18 Patient Breathing Valve

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).

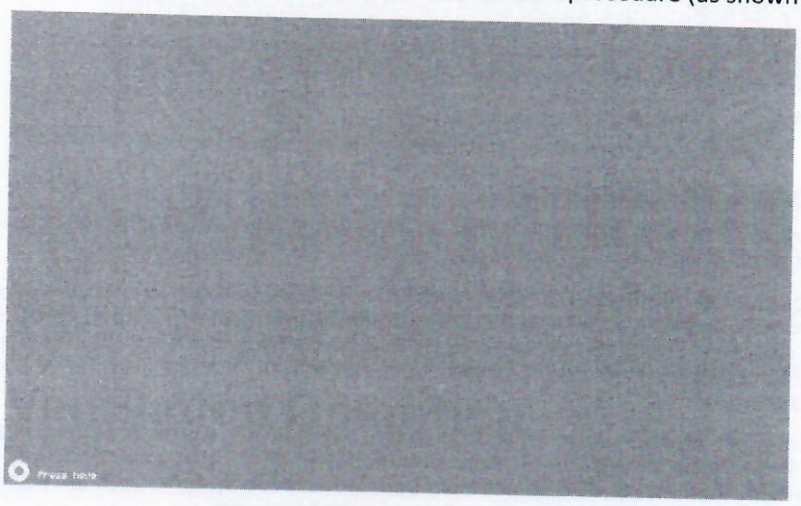


FIGURE 19 Click on the bottom left corner

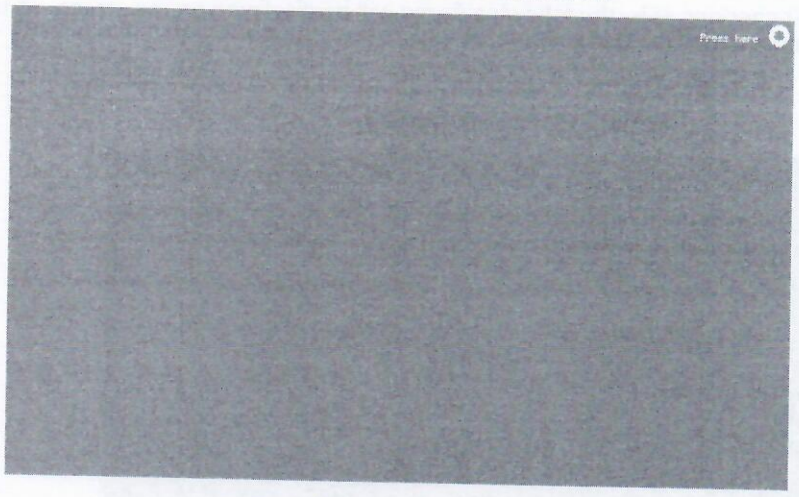


FIGURE 20 Click on the top right corner

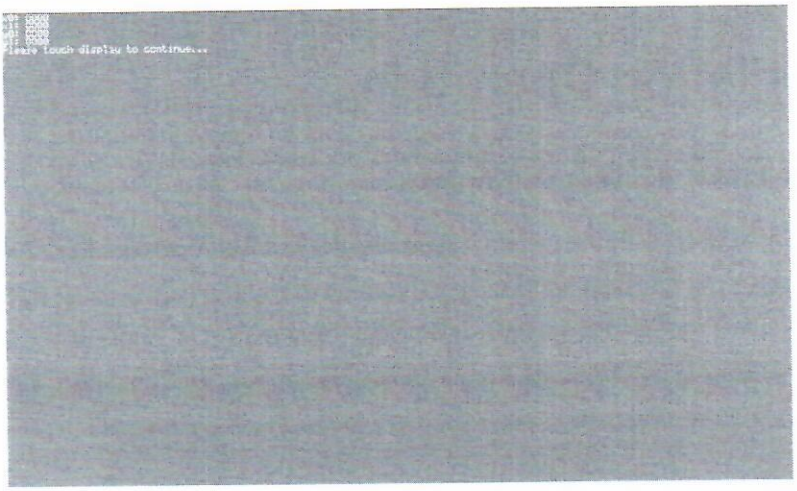


FIGURE 21 Click on any location

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

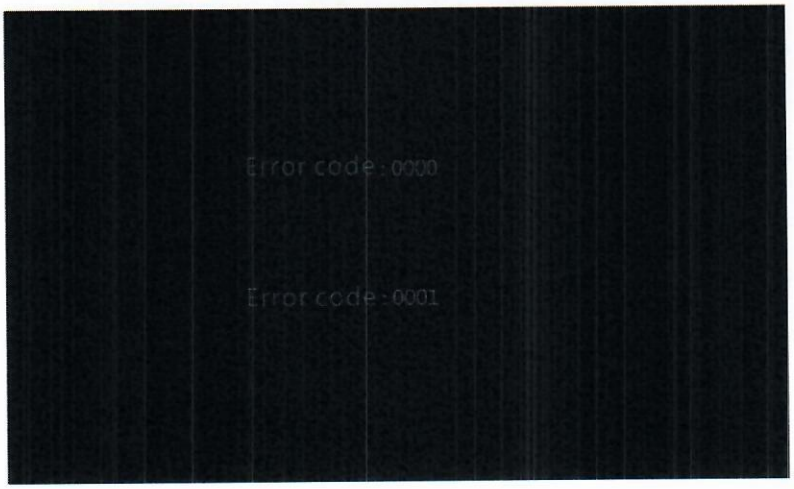


FIGURE 23 Error code

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).

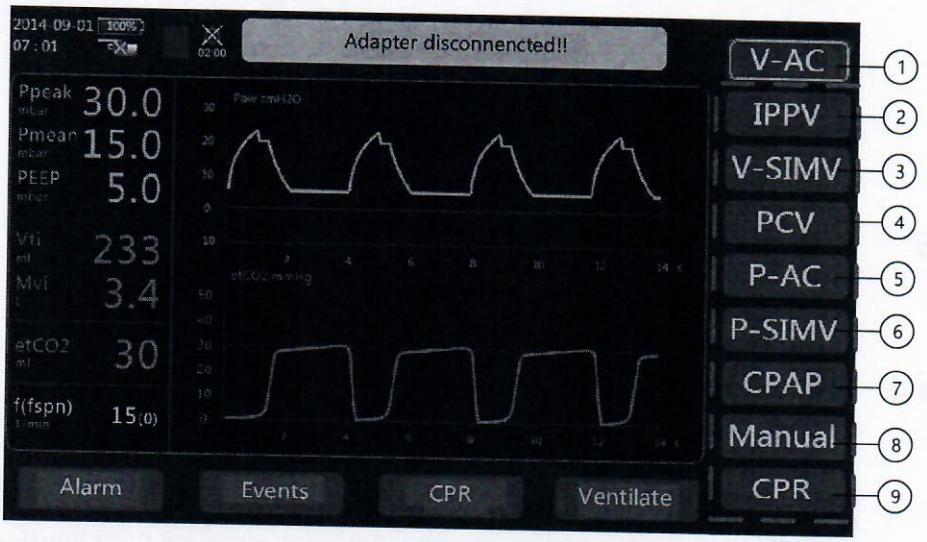


FIGURE 24 Ventilation Mode

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).

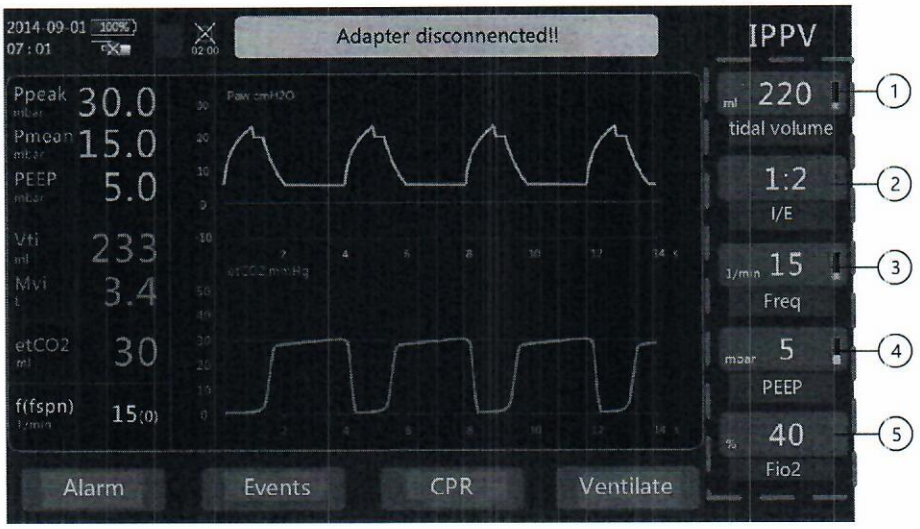


FIGURE 25 Main Ventilation Parameters

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:

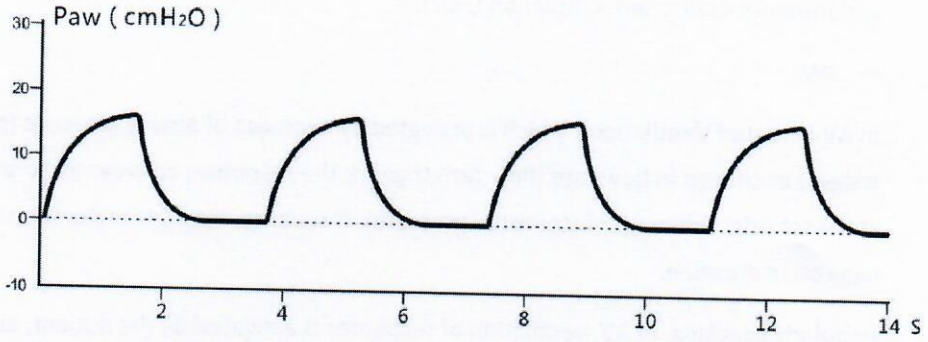


FIGURE 26 IPPV

- **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:

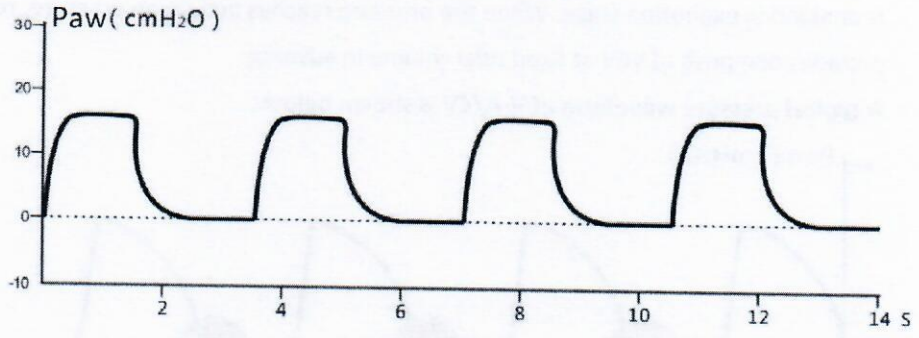


FIGURE 27 PCV

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:

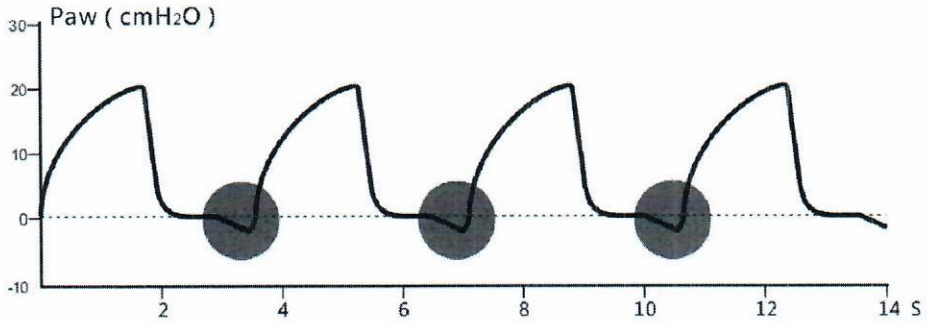


FIGURE 28 V-A/C

- **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:

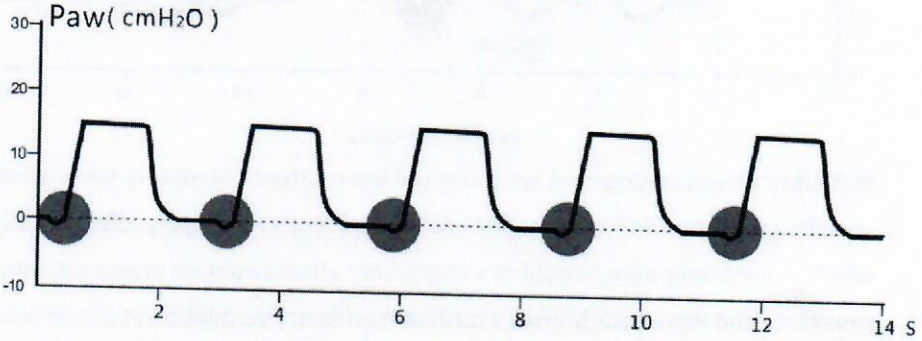


FIGURE 29 P-A/CV

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:

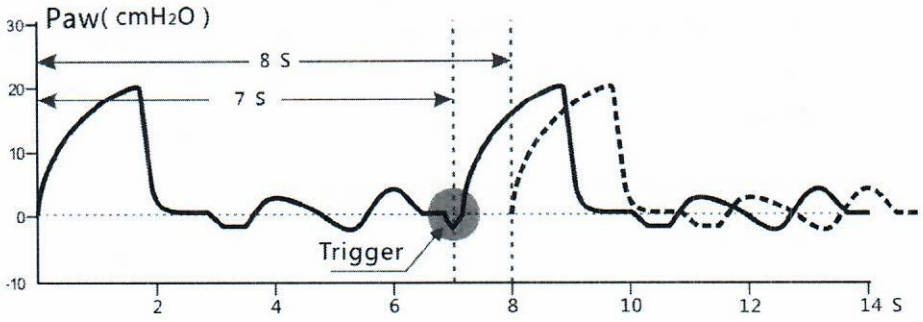


FIGURE 30 V-SIMV

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:

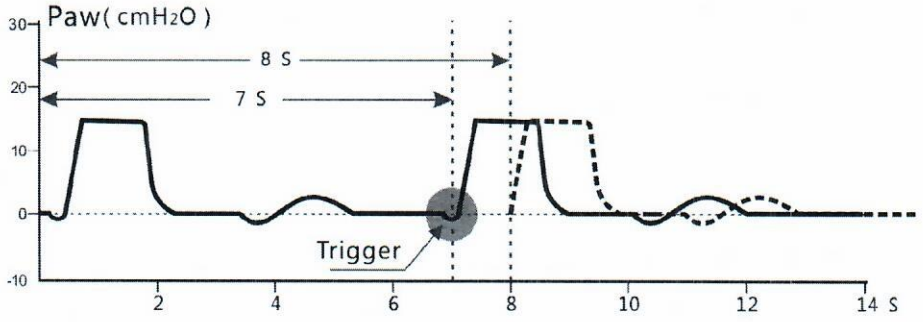


FIGURE 31 P-SIMV

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:

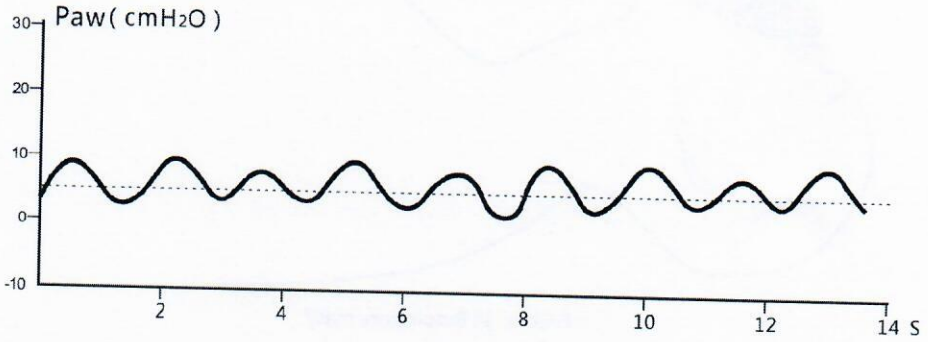


FIGURE 32 CPAP

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.

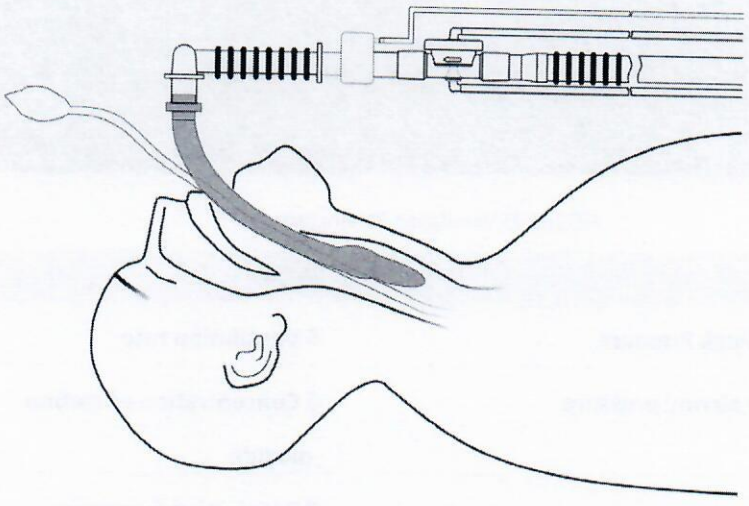


FIGURE 33 Intubation

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.

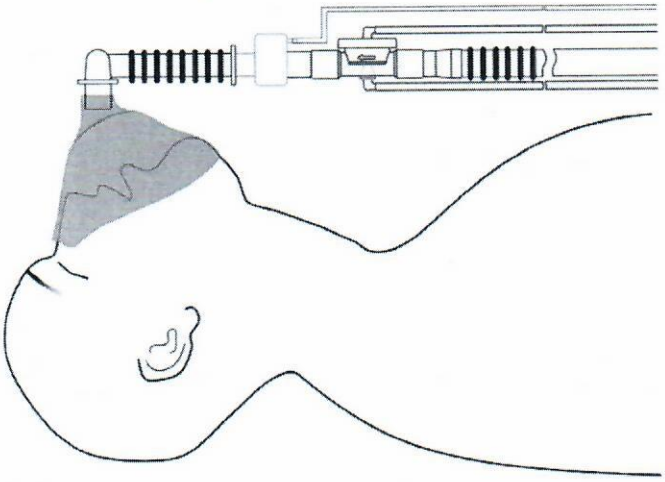


FIGURE 34 Respiratory mask

5.7 Monitoring of Respiration

5.7.1 Real-Time Ventilation Parameters

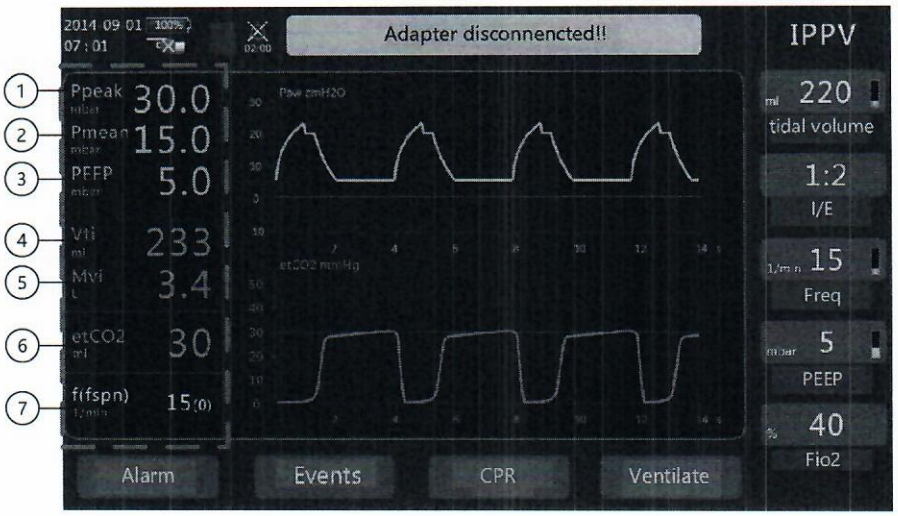


FIGURE 35 Ventilation Parameters

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

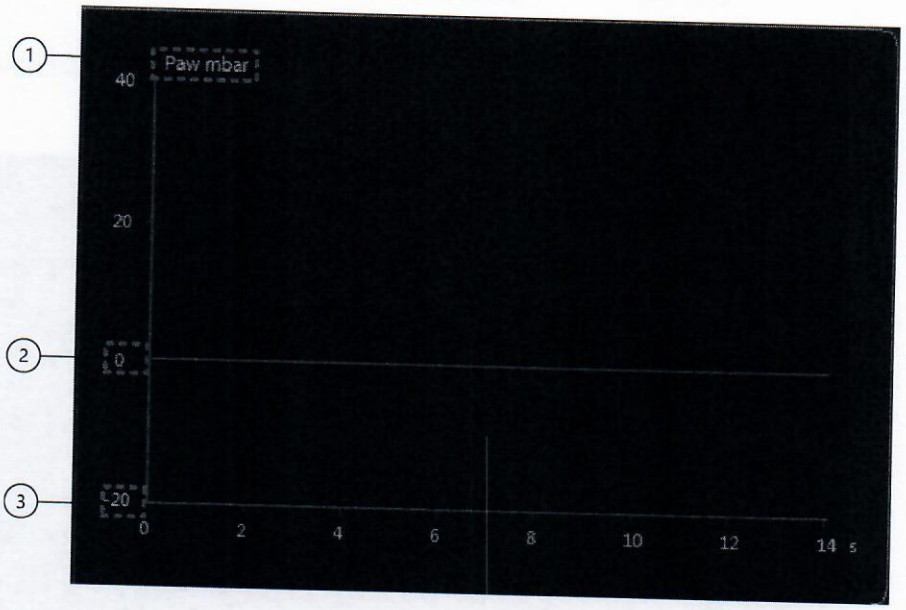


FIGURE 36 Waveform Diagram

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

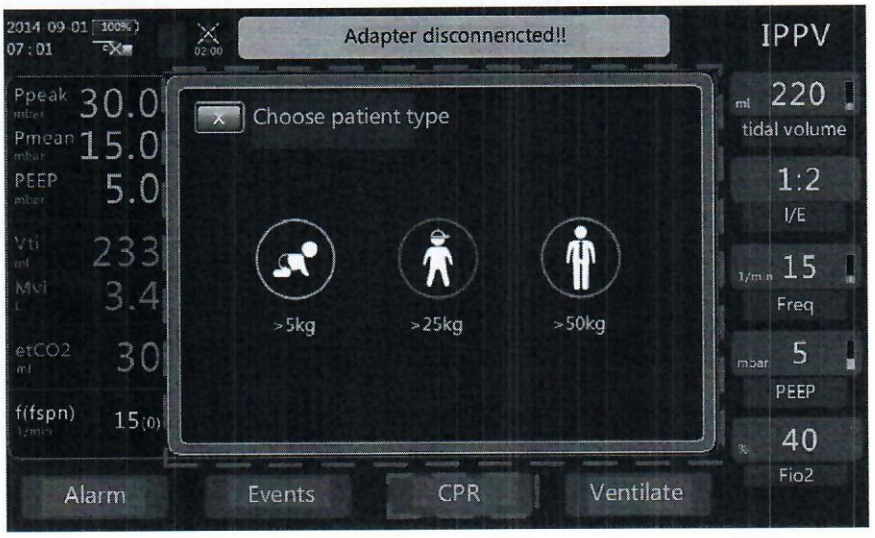


FIGURE 37 Select patient type

- **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 ".

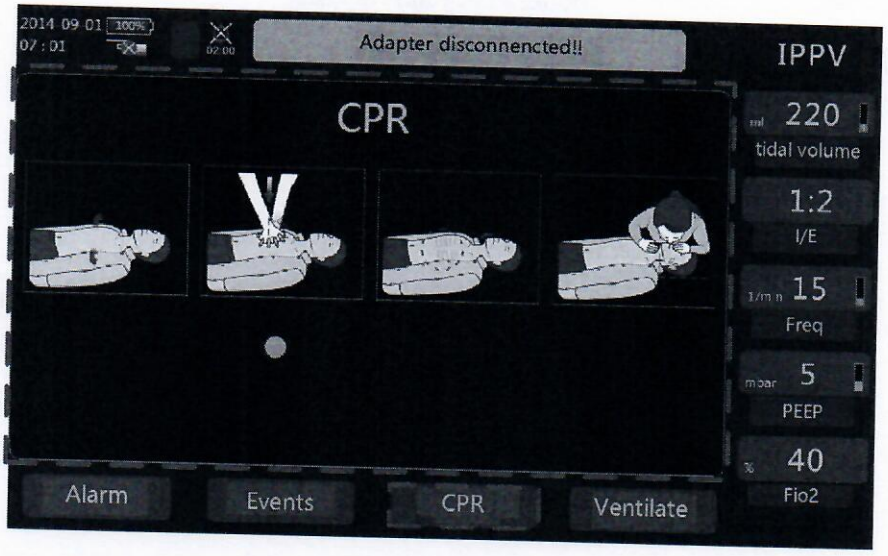


FIGURE 39 CPR

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.

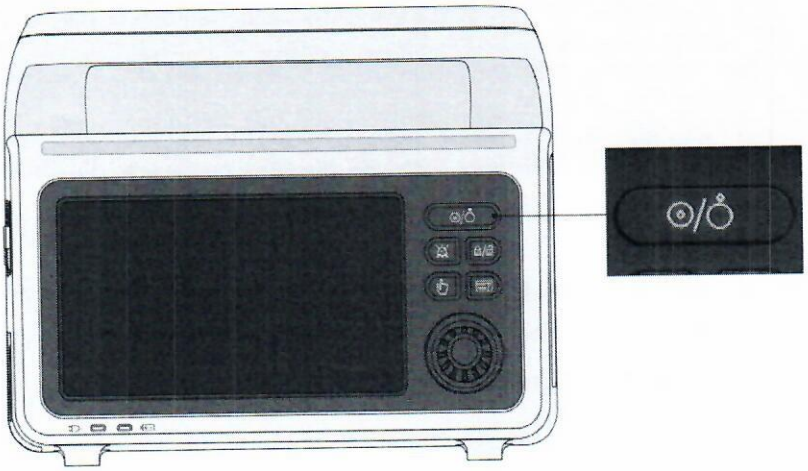


FIGURE 40 Shut down ventilator

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.

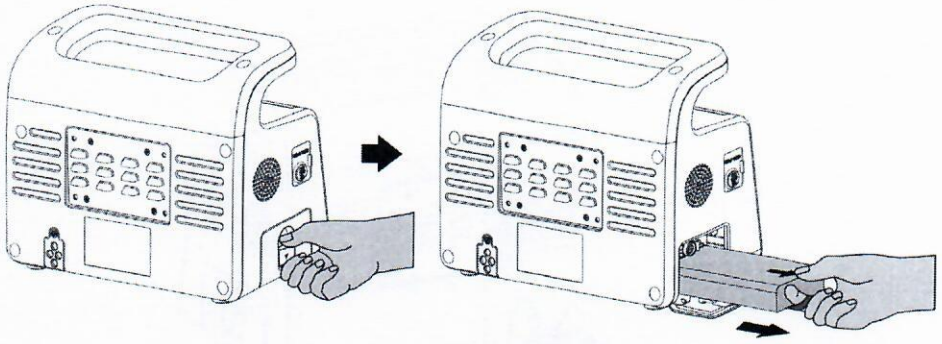


FIGURE 41 Replacement battery

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.

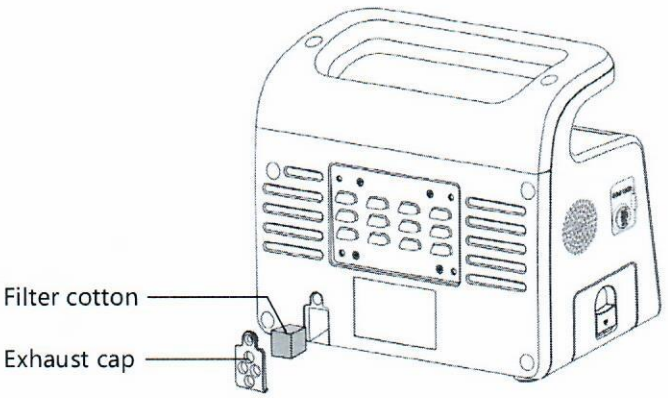


FIGURE 42 Replace Filter

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	o

Note: ● means standard configuration. o 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°C ~ 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

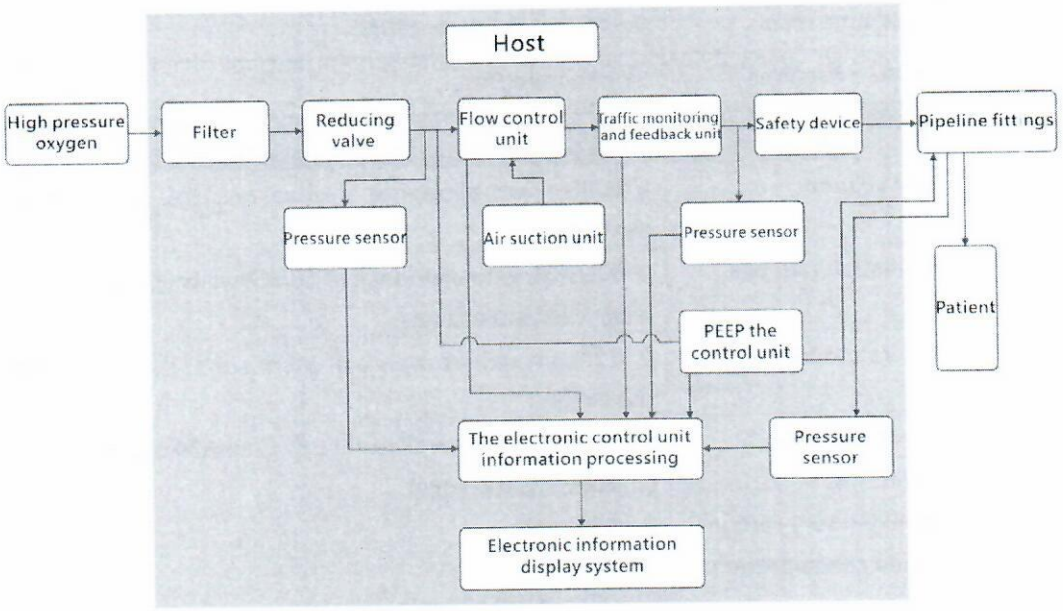


FIGURE 43 MUSCA x2 Product Structure Diagram

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.

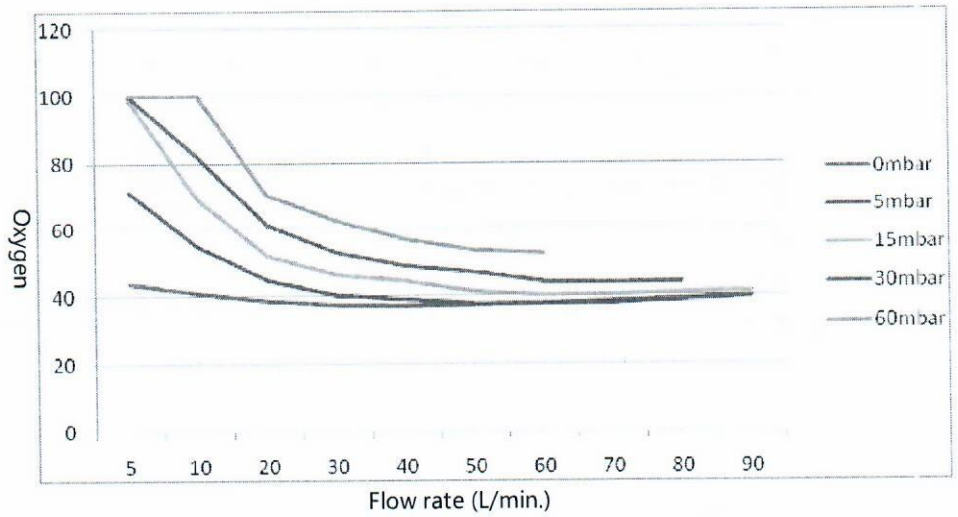


FIGURE 44 Minimum Oxygen Concentration

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	3 V (effective value) 150 kHz~80 MHz (except ISM bandsa)	3V (effective value)	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.
Radio frequency radiation GB/T 17626.3	10V (effective value) 150kHz~80MHz (ISM banda)	10V (effective value)	Recommended Distance $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$
	10V/m 80 MHz ~ 2.5 GHz	30V/m	$d = \left[\frac{12}{V2}\right]\sqrt{P}$ $d = \left[\frac{12}{E1}\right]\sqrt{P}$ 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		O	O	×	×	O	O
Packing Material		O	×	×	O	×	×
Main Unit	PCBA	O	O	×	O	O	O
	Interior Connecting Wires	O	O	O	O	O	O
	Machined Parts	O	O	O	×	O	O
Enclosure	Button	O	O	O	O	O	O
	Label	O	O	O	O	O	O
	Front Cover	O	O	O	O	O	O
	Rear Cover	O	O	O	O	O	O
Accessories	Air Hose	O	O	O	O	O	O
	Mask	O	O	O	O	O	O
	Corrugated Tube Assembly	O	O	O	O	O	O
	Air Source Hose Assembly	O	O	O	O	O	O
	Reservoir Bag	O	O	O	O	O	O
	Power Cable	O	O	O	O	O	O
	Connectors	O	O	O	×	O	O
	Vaporizer	O	O	×	O	O	O
	Jinn Bottle	O	O	O	O	O	O
	Steel Cylinder	O	×	×	O	O	O
	Flow Rate Sensor	O	O	O	O	O	O
	Oxygen Sensor	O	O	×	O	O	O

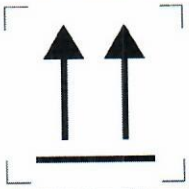
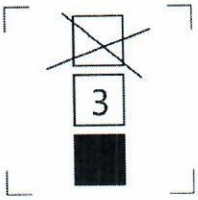
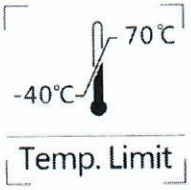
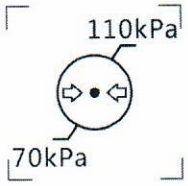
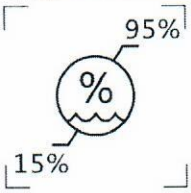
	CO2 Monitor	o	o	×	o	o	o

×: 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.

o: 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°C		
	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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medical

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