

ORDIN DE PLATA NR.: 1565

TIP.DOC. 1 :

DATA EMITERII:15 septembrie 2022:

PLATITI: 16000-00

LEI: Sasesprezece Mii lei 00 bani

PLATITOR: (R) "BIOSISTEM
MLD" S.R.L.

CONTUL DE PLATI/CODUL IBAN
MD95ML000000002251429243
CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR
BC"Moldindconbank"S.A. fil."Invest" Chisinau

CODUL BANCII:
:MOLDMD2X329:

BENEFICIAR (R) Centrul pen
tru achizitii publice central
izate in sanatate

CONTUL DE PLATI/CODUL IBAN
MD23TRPCCC518430B01859AA
CODUL FISCAL :1016601000212 /

PRESTATORUL BENEFICIAR
Ministerul Finantelor - Trezoreria de Stat

CODUL BANCII:
:TREZMD2X :

DESTINATIA PLATII:/P102/16000,00 Pentru :
garantia pentru oferta la procedura de a:
chizi?ie publica nr. ocds-b3wdp1-MD-1659:
684146195 din 15.09.2022

TIPUL TRANSFERULUI :
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:101:

DATA PRIMIRII:15/09/2022
DATA EXECUTARII:

SEMNATURILE
EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB:

DQEHAaCCBGwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSq:

SIB3DQEBCwUAMCIxIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4:

DTIxMDEyODExMzgwNVVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRAw:
gYDVQQIEwdNb2xkb3ZHMREwDwYDVQQHEWhDaGlzaw5hdTEWMBQGA1UEChMNQmIv

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIGWDCBlQAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBHAwggRSMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:
SIB3DQEBCwUAMCIxIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzkwOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZHMREwDwYDVQQHEWhDaGlzaw5hdTEWMBQGA1UEChMNQmIv

L.S.

(semnatura electronica)

CONDUCATOR:

(semnatura manuala)

CONTABIL-SEF:

(semnatura manuala)

SEMNATURA PRESTATORUL

L.S.

MOTIVUL REFUZULUI

L.S.

Digitally signed by Poiata Vitalie
Date: 2022.09.15 12:47:30 EEST
Reason: MoldSign Signature
Location: Moldova



CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ A2216457

din
от 06.09.2022

1. Destinația / Назначение

Pentru participarea la proceduri de achiziții publice

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea Наименование	Codul fiscal / Numărul de identificare Фискальный код / Идентификационный номер
BIOSISTEM MLD S.R.L.	1010600028048
Adresa sediului de bază (strada, numărul) Адрес основного месторасположения (улица, номер)	Codul - Denumirea localității Код - Наименование населенного пункта
Albisoara nr.16 bl.1 of.7	0150-SEC.RISCANI

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat /
Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет:
0,00 lei/лей.

4. Valabil până la / Действителен до 21.09.2022

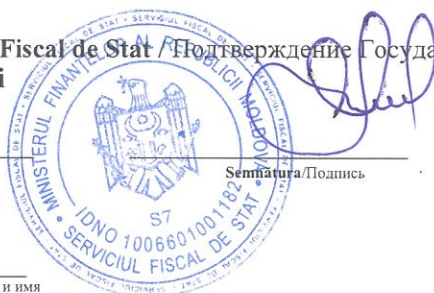
5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы

Șef DDF Rîșcani
a DGDF

Funcția/Dолжность

L.Ș/M.П. **Claudia GOJAN**

Executor: **061.4022)823402**
Numele și prenumele/Фамилия и имя



Semnătura/Подпись

Ana STOICOV

Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 06.09.2022 ora 14:01:17
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,00)



BC "MOLDINDCONBANK" S.A.

Filiala "Invest"

Republica Moldova, MD-2068
mun. Chișinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 - 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московской, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent în moneda națională al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML000000002251429243**.

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"
— ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT —

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

Svirepova Ludmila, registrator

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

L. Svirepova
semnătura

MD 0101250





I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. 8506 din 28.04.2021

Denumirea completă: **Societatea cu Răspundere Limitată «BIOSISTEM MLD».**

Denumirea prescurtată: **«BIOSISTEM MLD» S.R.L.**

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

Sediul: **MD-2001, str. Albișoara, 16/1, ap.(of.) 7, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1 Activitatea farmaceutică;**
- 2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;**
- 4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;**
- 5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;**
- 6 Consultații în domeniul sistemelor de calcul.**

Capitalul social: **5400 lei.**

Administrator: POIATA VITALIE,

Asociați:

- 1. POIATA VITALIE 33,40 %**
- 2. NASEDCHIN ALEXANDR 33,30 %**
- 3. KOJEVNIKOV DMITRII 33,30 %.**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 28.04.2021.

Specialist coordonator
tel. 022-207-840



Lazari Aliona



EB 0358735

Lista fondatorilor Biosistem-mld SRL

Nr.	Nume, Prenume	IDNP
1.	Vitalie Poiata	0983103892591
2.	Alexandr Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362



AGENȚIA DE MEDIU

ENVIRONMENTAL AGENCY

MD-2005 mun.Chișinău, str. Albișoara, 38
Tel. (022) 820-770, Email: am@am.gov.md

CONFIRMARE

privind înregistrarea în „Lista producătorilor” de produse
supuse reglementărilor de responsabilitate extinsă a producătorului
(echipamente electrice și electronice)

În scopul plasării pe piață a produselor de echipamente electrice și electronice, în conformitate cu prevederile art. 12 alin. (5) și alin. (14) lit. b) din Legea nr. 209 din 29.07.2016 privind deșeurile, și punctele 46 – 50 din Regulamentul privind deșeurile de echipamente electrice și electronice, aprobat prin Hotărârea Guvernului nr. 212 din 07.03.2018, se emite numărul de înregistrare

MD2021-10-EEE-005

pentru BIOSISTEM MLD, IDNO: 1010600028048, cu adresa juridică: mun. Chișinău, str. Albișoara 16/1, ap. 1.

Numărul de înregistrare este valabil începând cu data de 02.11.2021 până la data de 02.11.2024.

Director adjunct interimar
Gavril GÎLCA

SITUAȚIILE FINANCIARE
pentru perioada 01.01.2021 - 31.12.2021

Entitatea: BIOSISTEM MLD S.R.L.
Cod CUIO: 40717392
Cod IDNO: 1010600028048

Sediul:
MD:
Raionul(municipiul): 106, DDF RISCANI
Cod CUATM: 0150, SEC.RISCANI
Strada: SECTORUL RISCANI STR.Albisoara nr.16 bl.1 of.7

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice
Forma de proprietate: 16, Proprietate colectivă
Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:
Telefon: +37322808719
WEB:
E-mail: zmii13@mail.ru
Numele și coordonatele al contabilului-șef: DI (dna) Tel.

Numărul mediu al salariaților în perioada de gestiune: 3 persoane.

Persoanele responsabile de semnarea situațiilor financiare* Nasedchin Alexandr

Unitatea de măsură: leu

BILANȚUL

Anexa 1

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
	A C T I V			
	ACTIVE IMOBILIZATE			
	I. Imobilizări necorporale			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020		
	din care:	021		
	2.1. concesiuni, licențe și mărci			
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023		
	2.4. alte imobilizări necorporale	024		
	3. Fond comercial	030		
	4. Avansuri acordate pentru imobilizări necorporale	040		
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050		
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060		
	2. Terenuri	070		
	3. Mijloace fixe, total	080	2793637	3559998
	din care:	081		
	3.1. clădiri			
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	2791637	3533108
	3.4. mijloace de transport	084		

A.	3.5. inventar și mobilier	085		26890
	3.6. alte mijloace fixe	086	2000	
	4. Resurse minerale	090		
	5. Active biologice imobilizate	100		
	6. Investiții imobiliare	110		
	7. Avansuri acordate pentru imobilizări corporale	120		1162136
	Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	2793637	4722134
	III. Investiții financiare pe termen lung			
	1. Investiții financiare pe termen lung în părți neafiliate	140		
	2. Investiții financiare pe termen lung în părți afiliate, total	150		
	din care:			
	2.1. acțiuni și cote de participație deținute în părțile afiliate	151		
	2.2 împrumuturi acordate părților afiliate	152		
	2.3 împrumuturi acordate aferente intereselor de participare	153		
	2.4 alte investiții financiare	154		
	Total investiții financiare pe termen lung (rd.140 + rd.150)	160		
	IV. Creanțe pe termen lung și alte active imobilizate			
	1. Creanțe comerciale pe termen lung	170		
	2. Creanțe ale părților afiliate pe termen lung	180		
	inclusiv: creanțe aferente intereselor de participare	181		
	3. Alte creanțe pe termen lung	190		
	4. Cheltuieli anticipate pe termen lung	200		
	5. Alte active imobilizate	210		
	Total creanțe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220		
	TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220)	230	2793637	4722134
B.	ACTIVE CIRCULANTE			
	I. Stocuri			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	51978	5346
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	7221203	9147976
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	7273181	9153322
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	3912218	2182471
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	74631	208171
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350	2	
	7. Alte active circulante	360	5756117	1608597
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	9742968	3999239
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți neafiliate	380		
	2. Investiții financiare curente în părți afiliate, total	390		
	din care:			
	2.1. acțiuni și cote de participație deținute în părțile afiliate	391		
	2.2. împrumuturi acordate părților afiliate	392		
	2.3. împrumuturi acordate aferente intereselor de participare	393		

	2.4. alte investiții financiare în părți afiliate	394		
	Total investiții financiare curente (rd.380 + rd.390)	400		
	IV. Numerar și documente bănești	410	3942779	9861933
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	20958928	23014494
	TOTAL ACTIVE (rd.230 + rd.420)	430	23752565	27736628
	P A S I V			
C.	CAPITAL PROPRIU			
	I. Capital social și neînregistrat			
	1. Capital social	440	5400	5400
	2. Capital nevărsat	450	()	()
	3. Capital neînregistrat	460		
	4. Capital retras	470	()	()
	5. Patrimoniul primit de la stat cu drept de proprietate	480		
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	5400	5400
	II. Prime de capital	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
	3. Alte rezerve	530		
	Total rezerve (rd.510 + rd.520 + rd.530)	540		
	IV. Profit (pierdere)			
	1. Corecții ale rezultatelor anilor precedenți	550	X	
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	20060126	16230339
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	10403995
	4. Profit utilizat al perioadei de gestiune	580	X	()
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	20060126	26634334
	V. Rezerve din reevaluare	600		
	VI. Alte elemente de capital propriu	610		
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	20065526	26639734
D.	DATORII PE TERMEN LUNG			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640		
	din care:	641		
	2.1. împrumuturi din emisiunea de obligațiuni			
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643		
	3. Datorii comerciale pe termen lung	650		
	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700		
	DATORII CURENTE			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720		

E.	din care:	721		
	2.1. împrumuturi din emisiunea de obligațiuni			
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	3252667	343711
	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	188105	355528
	6. Datorii față de personal	760	50	350
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	187676	150263
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	58541	247042
	TOTAL DATORII CURENTE (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	3687039	1096894
F.	PROVIZIOANE			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clientilor	840		
	3. Provizioane pentru impozite	850		
	4. Alte provizioane	860		
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870		
	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	23752565	27736628

SITUAȚIA DE PROFIT ȘI PIERDERE

de la pînă la

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	25963175	38680547
din care:			
venituri din vânzarea produselor și mărfurilor	011	25044358	37724557
venituri din prestarea serviciilor și executarea lucrărilor	012	918817	951393
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016		4597
Costul vânzărilor, total	020	15186814	24434231
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	15186814	24433364
costul serviciilor prestate și lucrărilor executate terților	022		
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzărilor	026		867
Profit brut (pierdere brută) (rd.010 - rd.020)	030	10776361	14246316
Alte venituri din activitatea operațională	040	247603	5189
Cheltuieli de distribuire	050	19740	6076
Cheltuieli administrative	060	1259776	1788732
Alte cheltuieli din activitatea operațională	070	640169	1870642
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	9104279	10586055

Venituri financiare, total	090	519239	1517765
din care:			
venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	093	25612	30619
inclusiv: veniturile obținute de la părțile afiliate	094		
venituri din alte investiții financiare pe termen lung	095		
inclusiv: veniturile obținute de la părțile afiliate	096		
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097		
venituri din ieșirea investițiilor financiare	098		
venituri aferente diferențelor de curs valutar și de sumă	099	493627	1487146
Cheltuieli financiare, total	100	597528	249562
din care:			
cheltuieli privind dobânzile	101		
inclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103		
cheltuieli aferente ieșirii investițiilor financiare	104		
cheltuieli aferente diferențelor de curs valutar și de sumă	105	597528	249562
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	-78289	1268203
Venituri cu active imobilizate și excepționale	120		
Cheltuieli cu active imobilizate și excepționale	130		
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	-78289	1268203
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	9025990	11854258
Cheltuieli privind impozitul pe venit	170	1051159	1450263
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	7974831	10403995

SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la pînă la

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrșitul perioadei de gestiune
1	2	3	4	5	6	7
I.	Capital social și neînregistrat					
	1. Capital social	010				
	2. Capital nevărsat	020	()	()	()	()
	3. Capital neînregistrat	030				
	4. Capital retras	040	()	()	()	()
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
II.	Prime de capital	070				
III.	Rezerve					
	1. Capital de rezervă	080				
	2. Rezerve statutare	090				
	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
	Profit (pierdere)					
	1. Corecții ale rezultatelor anilor precedenți	120	X			

IV.	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130			
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X		
	4. Profit utilizat al perioadei de gestiune	150	X	()	()
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160			
V.	Rezerve din reevaluare	170			
VI.	Alte elemente de capital propriu	180			
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190			

SITUAȚIA FLUXURILOR DE NUMERAR

de la pînă la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vânzări	010		
Plăți pentru stocuri și servicii procurate	020		
Plăți către angajați și organe de asigurare socială și medicală	030		
Dobînzi plătite	040		
Plata impozitului pe venit	050		
Alte încasări	060		
Alte plăți	070		
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080		
Fluxuri de numerar din activitatea de investiții			
Încasări din vânzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobînzi încasate	110		
Dividende încasate	120		
inclusiv: dividende încasate din străinătate	121		
Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150		
Plăți aferente rambursării creditelor și împrumuturilor	160		
Dividende plătite	170		
inclusiv: dividende plătite nerezidenților	171		
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200		
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210		
Diferențe de curs valutar favorabile (nefavorabile)	220		
Sold de numerar la începutul perioadei de gestiune	230		
Sold de numerar la sfîrșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

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Расписка 2

Респондент

Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.

Предоставил отчёт: RSF1_21

На фискальный период: A/2021

Дата предоставления: 29.03.2022

Временная метка отчёта зарегистрированного в Информационной Системе НБС : 29.03.2022 17:25:45

National Bureau of Statistics (NBS) received the electronic version of the report, sent by you. The data provided is verified by NBS.

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Расписка

Респондент

Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.

Предоставил отчёт: RSF1_21

На фискальный период: A/2021

Дата предоставления: 29.03.2022

Временная метка отчёта зарегистрированного в Системе Электронной Отчётности и отправленного в Информационную Систему БНС : 29.03.2022 14:51:06



SAVER **ONE** SERIES the new generation

USER MANUAL



life is a breath,
...keep it safe with us

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These instructions cannot be reproduced, transmitted, stored electronically or translated into another language or computer language, entirely or partially, without our consent.

Infringing this prohibition does not only violate our copyright, but also reduces our ability to provide accurate and timely information to the user and the operator of this device.

Version NG2.0 issued on 01/02/2013

The contents of this user manual are subject to change without notice.

A.M.I. Italia Srl
Via Cupa Reginella, 15
80010 Quarto (NA)
Italia

Printed in Italy

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CHAPTER 1: Basic Instructions for SAVER ONE AED Series

1.1 PREFACE

This Manual is modular. When complete, it provides instructions on the entire SAVER ONE AED Series produced by A.M.I. Italia Srl, which includes the following AED models:

- **SAVER ONE** Semi-Automatic and Fully Automatic Public Access Defibrillator
- **SAVER ONE D** AED with ECG Monitoring (with TFT colour display)
- **SAVER ONE P** AED with ECG Monitoring & Manual Override (with TFT colour display)

SAVER ONE AED Series shares a basic set of instructions and common features which can be combined in just one chapter (CHAPTER 1) of this Manual.

Separated chapters, one for each model of AED, can be integrated to CHAPTER 1 in order to form various Manuals, one for each individual model of AED, as follows:

- Chapters 1 and 2 for SAVER ONE
- Chapters 1 and 3 for SAVER ONE D
- Chapters 1 and 4 for SAVER ONE P
- Chapters 1, 2, 3 and 4 for the complete SAVER ONE AED Series

1.1.1 Product Models

Thank you for choosing one of the Saver One AED model manufactured by A.M.I. Italia Srl.

Please read carefully the instructions given in this Manual so that you can use the device properly, according to its function and indication of use. It is important to respect the instructions given in this Manual in order to ensure the safety of the patient, the rescuer and third persons while using the device.

1.1.2 Contact Information

You can contact our Company through the website www.amiitalia.com or to the following addresses:

HEAD REGISTERED OFFICE

Centro Direzionale Isola A7
80100 Napoli (NA)
Italy

NORTH ITALY OFFICE

Marketing & Public Relations

Viale Gran Sasso, 11
20131 Milano
Tel: +39.02.20509246
Fax: +39.02.29520839

SOUTH ITALY OFFICE

Production & Service

Via Cupa Reginella, 15
80010 Quarto (NA)
Tel: +39.081.8063475 / 081.8060574
Fax: +39.081.8764769

To order additional AEDs or accessories worldwide:

Tel: +39.081.8063475
Fax: +39.081.8764769
Email: info@amiitalia.com

To receive customer support (please have the AED model and its Serial Number available when contacting Customer Service. The Serial Number is located on the label, underside the device):

Tel: +39.081.8060574
Fax: +39.081.8764769
Email: support@amiitalia.com

1.1.3 Limited Warranty

A.M.I. Italia Srl, warrants that its SAVER ONE AED Series and related Accessory will be free from defects in material and workmanship, under normal use and maintenance, according to the terms and conditions of this warranty. This Limited Warranty is only granted to the original purchaser and is not transferable or assignable to third parties. For purposes of this warranty, the original purchaser is deemed to be the original end-user of the product purchased.

Duration of Warranty

SAVER ONE AED Series has a warranty of six (6) years starting from the date of mailing to our facility of the "Warranty Card" or optionally starting from thirty (30) days after the date of the shipment from our facility to the original purchaser (will attest what is chronologically occurring first).

The non-rechargeable Li-SOCl₂ battery (SAV-C0903) has a warranty of five (5) years starting from the date of production both for its Standby Life (typical when the battery is installed to the device: will power the AED in standby state within the specified standby temperature range, assuming 1 battery insertion test and no defibrillation uses) or its Shelf-Life (typical when stored within the specified temperature range with its original packaging).

The Li-Ion Rechargeable Battery (SAV-C0011) and the Charger (SAV-C0014) have a warranty of two (2) years starting from the date of production within the specified temperature range.

The Disposable Pads shall be warranted until their expiration date.

Any other Accessory is warranted for six (6) months starting from 30 days after the date of the original shipment.

Validation of Warranty

The original purchaser should validate the warranty of the device by completing the "Warranty Card" (included inside each original box packing) and by sending it with registered mailing back to our facility or optionally should register it in our web site: www.amiitalia.com

In case of defects covered by this warranty, the original purchaser must get in contact with the direct seller or with an Authorized Service Centre for obtaining RMA (return materials authorization). A.M.I. Italia Srl reserves at its sole discretion the exclusive right to repair or replace the device that proves defects by reason of improper workmanship or materials.

Exclusion of Warranty

This warranty does not cover defects or damages of any sort resulting from, but not limited to, accident, abuse, misuse, neglect, natural or personal disaster, alterations, improper installation or use, failure to follow instructions or warnings recommended by the manufacturer into the manual, unauthorized disassembly, repair or modification or replacements of parts.

This warranty is void if the device is used in conjunction with incompatible parts and Accessories not authorized by the manufacturer.

This warranty does not cover items and components subject to normal wear and burnout during use, including but not limited to buttons, lamps, fuses, battery contacts, patient cables and accessories.

This warranty will be automatically invalidated if:

- ✓ the serial number of the device is amended, deleted, become unreadable or otherwise tampered with
- ✓ the seal of guarantee has been removed from the device (opening the case)
- ✓ the products' trade name or the manufacturer's name has been covered, altered or deleted

This warranty does not cover the purchasing of used device(s). In this case A.M.I. Italia Srl is not responsible for any product defects and the warranty shall be offered by the seller of the used device(s).

Disclaimers

The foregoing is the complete warranty for A.M.I. Italia Srl device(s) and specifically excludes and replaces all other warranties and representations, whether oral or written.

No other warranties are made with respect to A.M.I. Italia Srl device(s) and A.M.I. Italia Srl expressly disclaims all warranties not stated herein, including, to the extent permitted by applicable law, any implied warranty of merchantability or fitness for a particular purpose.

This Limited Warranty will be the sole and exclusive remedy in relation to your device purchasing.

No person, including any Agent, Dealer or A.M.I. Italia Srl Representative, is authorized to make any representation or warranty concerning A.M.I. Italia Srl device(s), except to refer purchasers to this Limited Warranty. In no event will A.M.I. Italia Srl be liable to the purchaser of A.M.I. Italia Srl device(s) for any

damages, expenses, lost revenue, lost savings, lost profits or any other incidental or consequential damages arising from the purchase, use or inability to use the A.M.I. Italia Srl device(s), even if A.M.I. Italia Srl has been advised of the possibility of such damages.

Some states do not allow limitations on duration and exclusions or limitations of incidents or consequential damages, therefore the above limitation or exclusion may not apply to you.

Warnings

Install, use and perform maintenance on SAVER ONE AED Series exclusively following instructions given into the user's manual.

Legal Rights

This warranty gives to the original purchaser specific legal rights whenever AEDs are installed, used, maintained and stored exclusively following instructions given into the user's manual.

Place of Jurisdiction

This Limited Warranty is subject to Italian material and procedural law. Any dispute concerning this warranty or that might arise from the use of SAVER ONE AED Series shall be handled definitely by the court in Naples (Italy), which will be the place of jurisdiction for any legal action arising out of this warranty.

1.2 PRODUCT INFORMATION & SAFETY

1.2.1 Product References

For purposes of retaining simple and clear instructions in this manual, note the product references given. Features, specifications, operating instructions and maintenance common to all models will be referred to as: “AED” or “device” refers to **SAVER ONE** Semi-Automatic or Fully Automatic and to **SAVER ONE D** and **SAVER ONE P** unless otherwise specified.

1.2.2 AED Tracking

Defibrillator manufacturers and distributors are required to track the location of defibrillators they sell. Please notify A.M.I. Italia Srl Customer Service in the event that your AED is sold, donated, lost, stolen, destroyed or if it was not purchased directly from A.M.I. Italia or an authorized dealer.

1.2.3 Safety Terms

This manual contains symbols indicating potential hazard categories which definition is as follows:



HAZARD

reports an immediate risk to the safety of persons, which also involves death or damage to the device or parts thereof



WARNING

reports a situation or unsafe practice which involves serious injury to persons and damage to the device or its parts

1.2.4 Safety Descriptions

The following is a list of AED safety alerts that appear throughout this manual. Read and understand these safety alerts before operating the AED.



HAZARD

- According to the IEC standards, it is not allowed to use the device or its accessories in the presence of flammable substances (petrol or similar) or in an atmosphere enriched with oxygen or combustible gas/vapours.
- Do not recharge the non-rechargeable battery Li-MnO₂ (SAV-C0010) or Li-SOCl₂ (SAV-C0903), there may be the risk of explosions.
- Do not allow the battery to come into contact with open flames. Do not expose to fire.
- Do not short-circuit the battery terminals.
- In the event of leakage or strange odour from the batteries, keep them away from fire in order to prevent the ignition of any leaked chemical fluids.
- Danger of electric shock. The device generates high voltages and dangerous levels of current. Do not open the device, do not remove the panels and do not try to repair it. The AED does not have components that users can repair. For the purposes of repair, the device must be sent to an authorized service centre.
- Do not apply the defibrillation PADs on the chest of the patient if there are nitro-glycerine patches. Remove the patches and place the electrodes afterwards. Otherwise there is a risk of causing an explosion.

- Do not touch the patient and prevent third parties from coming into contact with the patient during defibrillation shock. Avoid any contact between:
 - parts of the patient's body
 - conductive liquids (such as gels, blood or salt solution)
 - metallic objects in the vicinity of the patient (such as a bed frame or stretching device) that represents pathways for unintentional defibrillation current.
- Do not immerse the AED, its parts or accessories, in water or other liquids.
- Do not allow the penetration of liquids into the AED, its parts or accessories. Avoid spilling liquids on the AED and its accessories: it may cause damage or risk of fire or electric shock. Do not sterilize the device or its accessories.



WARNING

- Avoid the formation of air bubbles between the skin and the defibrillation pads (electrodes). The formation of air bubbles during defibrillation can cause severe burns to the skin of the patient. To avoid the formation of air bubbles, make sure the pads completely adhere to the skin. Do not use electrodes whose gel is dried. Check the expiry date before use.
- The RF (radio frequency) interferences from devices, such as cell phones and two-way radios, can cause the malfunction of the AED. The device must be kept at least 2 meters away from RF devices, as specified in EN 61000-4-3. Keep a sufficient distance from other sources of therapeutic and diagnostic energy (e.g. diathermy, high-frequency surgery, magnetic tomography).
- Use the AED only if you received a BLS-D or ALS-D training course.
- Before using the device be sure there is no visible damage.
- The interface issues optically invisible infrared radiation. The diode emission complies with IEC 60825-1 Class “Eye Safe”.
- Do not use the SAV-C0016 defibrillation Paediatric pads on adult patients (older than 8 years old and weighing more than 25 kg). By using the paediatric pads, the AED automatically switches to the paediatric mode, reducing the maximum energy that can be delivered to 50J.
- Do not apply the defibrillation electrodes directly on a pacemaker to avoid any misinterpretation of the ECG and to avoid damage to the pacemaker through the shock.
- Do not allow the defibrillation pads to touch or come into contact with tampons, trans dermal patches, etc.. Failure to do so may result in the formation of electric arcs and patient skin burns during defibrillation, and even the loss of the current.
- Place the defibrillation pads as indicated in this manual and marked on the packaging.
- Do not use the defibrillation PADS if the gel is detached from the support or if it is torn, split or dry.
- If you have identified any damage on device and/or accessories, do not use the AED in any case.
- Before using AED remove metal objects from the patient's body (including necklaces or bracelets, etc.).
- Do not use other defibrillation pads than those provided by the manufacturer.

- Do not touch the patient or the defibrillation pads during the ECG analysis.
- Handling or transporting the patient during the ECG analysis performed by the device can lead to incorrect or delayed diagnosis. Minimize movement during the analysis phase. If the device is used while the ambulance is in motion, stop the car and start again only after delivering a shock.
- Avoid using the Adult defibrillation pads on children (aged 1-8 or weighing between 8-25kg).
- Before applying the defibrillation pads you have to dry the patient's chest and remove unwanted hair.
- Do not subject AED, its accessories and parts to falls and/or impacts.
- Do not use damaged accessories, otherwise they may cause the malfunction of the device.
- Using batteries, pads, cables or optional equipment other than those approved by A.M.I. Italia Srl may cause the AED to function improperly during a rescue.
- Avoid excessive rough handling of the device or its accessories or parts in order to avoid possible damage. Inspect the entire system periodically.
- Perform the sanitization of the device in accordance with the rules set out in this manual and in any case always verify that the device is switched off, with the battery disconnected and pads unconnected.
- The defibrillation pads are disposable, to be used only on one patient. Do not reuse it; throw them after use and replace them with a new pair.
- Intense or prolonged administration of cardiopulmonary resuscitation with the defibrillation pads applied to patient may damage the electrodes. Replace them if they are damaged during use or handling.
- Improper maintenance may damage the AED or cause it to malfunction. Follow the instructions in this manual.
- Use the non-rechargeable batteries Li-MnO₂ (SAV-C0010) or Li-SOCI₂ (SAV-C0903) manufactured by A.M.I. Italia Srl before their expiration date.
- The rechargeable Li-Ion (SAV-C0011) battery must be charged using only the CBACCS1 (SAV-C0012) charger model manufactured by A.M.I. Italia Srl Otherwise the batteries may be damaged.
- The CBACCS1 (SAV-C0012) Charger must be used only with the Meanwell power supply P66A-3P2JA (SAV-C0013) model provided by A.M.I. Italia Srl The use of different power supplies may result in incorrect operation of the charger and may damage the ACC (SAV-C0011) rechargeable batteries.
- Remove the batteries from the device only if the device is turned off for at least 5 seconds. Failure to do so could severely damage the device and the battery.
- The AED, its accessories and parts are not sterile and cannot be sterilized.
- Do not expose the device, its parts or accessories to direct light or high temperature.

1.2.5 Disposal

The device, its accessories and parts shall not be disposed of with other household waste within the European community. To prevent possible harm to the environment or human health caused by improper waste disposal, recycle this item responsibly in order to promote a sustainable use of resources. When disposing a used device use an appropriate waste collection service or return it to the dealer in the area. In this way it will be possible to carry out an environmentally safe recycling.

1.2.6 Symbols Description

The following symbols may appear in this manual, on the AED or on its accessories.
Some of the symbols represent standards and compliances associated with the AED and its use.

	ILCOR Universal Symbols for AED		IMQ Mark
	Danger High Voltage		CE mark with identification number
	General notices: Consult the accompanying documents before using the device		The equipment's degree of protection against dust and water (battery included)
	Type BF, Defibrillation equipment		Serial number
	Do not expose to high temperatures or flames		Manufacturing date
	Do not recharge		Lot Number (LOT)
	Do not open		Expiry date
	Do not destroy, or damage		Order Reference Number
	Do not use it in pools of water		The Manufacturer's name
	Read the User Manual		No Latex
	Battery recycling		Single use, do not reuse
	Please follow local regulations for waste disposal		Not Sterile
	Fragile		External indications on the box
	Store in a dry place		This side upwards
	Do not expose to direct sunlight		Temperature limits
	Danger of electric shock, do not open		Stack in height only up to 6 cartons

1.2.7 Electromagnetic compatibility

The AED is intended for use in the electromagnetic environment specified in the following paragraphs. The user of the device must ensure that it is used in such an environment as specified below.

Electromagnetic Emission

Emission test	Conformity	Electromagnetic environment (guide)
RF emissions CISPR 11	Group 1	The AED uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference with electronic devices. The AED is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Fluctuation voltage / Fluctuation emissions IEC 61000-3-3	Not applicable	

Electromagnetic Immunity

Immunity Test	IEC 60601-1 test level	Compliance Level	Electromagnetic Environment (guide)
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood or concrete or be fitted with ceramic tiles. If the floor is provided with synthetic material, the relative air humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	Not applicable	The quality of the supply voltage should correspond to that of a typical environment of a business building or hospital.
Surge IEC 61000-4-5	± 1 kV voltage in antiphase ±2 kV isophase voltage	Not applicable	The quality of the supply voltage should correspond to that of a typical environment of a business building or hospital.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for ½ cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5seconds	Not applicable	The quality of the supply voltage should correspond to that of a typical environment of a business building or hospital.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields in the network frequency should correspond to typical values found in the environment of office buildings or hospital.

Electromagnetic Immunity (continued)

Immunity Test	IEC 60601-1 test level	Compliance Level	Electromagnetic Environment (guide)
			Portable or mobile RF communications equipment should not be used near to any part of the AED, including cables. Then you have to calculate the separation distance recommended by the applicable equation to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz up to 80MHz outside ISM bands ^a	3 Vrms	$d = 1.2\sqrt{P}$
	10 Vrms 150kHz up to 80MHz within ISM bands ^a	10 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-6	10 V/m 80 MHz up to 2.5 GHz	10 V/m	$d = 1.2\sqrt{P}$ from 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ from 800 MHz to 2.5 GHz Where P is the maximum power produced by the watt transmitter (W) according to the manufacturer of the transmitter and d is the separation distance in meters (m) ^b The force fields of the fixed RF transmitters as determined by an electromagnetic survey in situ ^c, should be less than the frequency interval ^d. Interference may occur in the vicinity of equipment marked with this symbol: 
NOTE 1: At 80 MHz and 800 MHz, the applied separation distance is the one used for very frequent intervals. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is influenced by the absorption and reflection from structures, objects and people.			
A	The ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz up to 6.795 MHz, 13.553 MHz up to 13.567 MHz, 26.957 MHz up to 27.283 MHz and 40.66 MHz up to 40.70 MHz		
B	The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range from 80 MHz to 2.5 GHz are intended to reduce the likelihood of mobile/portable communication equipment to cause problems if they are inadvertently brought into the area of the patient. For this reason the additional factor of 10/3 is applied in the calculation of the protection distances recommended in these frequency areas		
C	Force fields arising from fixed transmitters, such as radio stations (mobile/cordless) for telephones and mobile radios, amateur radio, AM and FM radio stations and TV channels can be theoretically estimated with accuracy; A survey should be considered for assessing the impact of electromagnetic waves on the environment due to fixed RF wave transmitters. If the measured field in which the AED is located is higher than the applicable compliance level, you should observe the device to prove the operation complies with the provisions. In case of any malfunctions, additional measures are needed, such as reorienting or providing a new location for the AED.		
D	Over the frequency range between 150kHz and 80MHz, the force fields should be less than 3 V/m		

Recommended separation distance between mobile RF communications equipment and the AED

The AED is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AED as recommended below, according to the maximum output power generated by the communications equipment.

Maximum emission rate of the transmitter W	Separation distance according to the transmitter's frequency m			
	150kHz to 80 MHz Outside ISM bands $d = 1.2\sqrt{P}$	150kHz to 80 MHz Within ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12 m	0.12 m	0.12 m	0.23 m
0.1	0.37 m	0.38 m	0.38 m	0.73 m
1	1.12 m	1.2 m	1.2 m	2.3 m
10	3.7 m	3.8 m	3.8 m	7.3 m
100	12 m	12 m	12 m	23 m
For transmitters estimated at a maximum power that is not listed above, the recommended separation distance “d” in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum power produced by the transmitter watts (W) according to the transmitter's manufacturer.				
NOTE 1:	At 80 MHz and 800 MHz, the applied separation distance is the one used for very frequent intervals.			
NOTE 2:	The ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz up to 6.795 MHz, 13.553 MHz up to 13.567 MHz, 26.957 MHz up to 27.283 MHz and 40.66 MHz up to 40.70 MHz			
NOTE 3:	An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range from 80 MHz to 2.5 GHz to decrease the chance that a mobile/portable communications equipment could cause interference if it is inadvertently brought into the patient's areas.			
NOTE 4:	These guidelines may not apply in all situations. Electromagnetic propagation is influenced by the absorption and reflection from structures, objects and people.			

1.3 INTRODUCTION

This section presents information about the AED, its use, and the training requirements for operation.

1.3.1 AED Description

The AED is a self-testing, battery-operated Automated External Defibrillator.

Once applied the defibrillation pads (electrodes) to the patient's bare chest, the AED automatically performs an analysis of the patient's electrocardiogram (ECG) and advises the operator to deliver a shock, if needed.

The AED guides the operator through the rescue using a combination of voice prompts, audible alerts, and visible indicators.

1.3.2 Indications for use

The AED is a medical device intended to be used by personnel who have been trained in its operation.

User should be qualified by training in basic life support or other physician authorized emergency medical response.

The device should only be used when a suspected cardiac arrest victim has an apparent lack of circulation as indicated by:

1. Unconsciousness, and
2. Absence of normal breathing, and
3. Absence of a pulse or signs of circulation.

When a patient is a child (age <8 years or weighing <25Kg) the device should be used with the Paediatric defibrillation pads, in order to attenuate the delivered energy. Therefore, the therapy should not be delayed to determine the patient's exact age or weight.

1.3.3 Rescue Protocol

The AED rescue protocol is consistent with the guidelines in force and recommended by the ERC (European Resuscitation Council) and the AHA (American Heart Association).

Upon detecting a shockable cardiac rhythm, the AED advises the operator to press the SHOCK button (Semi-Automatic models only) to deliver a defibrillation shock followed by performing 2 minutes of CPR.

For the SAVER ONE Fully Automatic model, upon detecting a shockable rhythm, the AED will automatically deliver defibrillation shocks followed by performing 2 minutes of CPR.

1.3.4 Energy Protocols

The Adaptive BTE (biphasic truncated exponential) will deliver variable escalating energy conforming to patient chest's impedance.

Each AED model of the SAVER ONE series can be produced with 2 energy versions:

- **STANDARD** with energy level **maximum at 200J**
- **POWER** with energy level **maximum at 360J**

Therefore, in accordance to what purchased, the AED could be equipped with the following factory default adult shock sequence:

- **150J – 200J – 200J** for the STANDARD version
- **200J – 250J – 360J** for the POWER version

The paediatric energy protocol will be fixed at 50J if Paediatric defibrillation pads are installed.

The AED senses when Paediatric electrodes are connected to the device and will automatically adjust to use a more appropriate lower energy level (50J).

1.4 GETTING STARTED

This section presents information on unpacking and the AED activation, on essential parts and accessories and provides a complete overview on self-tests.

1.4.1 Unpacking and Inspecting

The AED can be equipped with different configurations, therefore the box contents may differ according to the configuration ordered.

To be sure that your order is correct verify the contents of the box against your packing slip.

If you have any questions about your order contact our Customer Service or the local Distributor.

1.4.2 AED Modes

Operating Mode:	Defined as having the battery installed and device is switched on. This is the mode the AED would be in during an actual rescue situation.
Standby Mode:	When the battery is installed but the device is switched off. In this mode the AED is not being used in a rescue. The device will conduct its routine self-tests to ensure proper operation.
Storage Mode:	When the battery is removed such as during shipping or transport. With the battery removed, the AED is unable to perform self-tests or rescues.



BEING A LIFE-SAVING DEVICE, THE AED SHOULD ALWAYS BE AVAILABLE FOR USE. ONCE PURCHASED, IT'S GOOD PRACTICE TO ACTIVATE IT, INSTALLING THE BATTERY, AND KEEP IT IN STANDBY MODE.

1.4.3 Battery Options

The AED can work with both these two types of batteries:

- (SAV-C0903) Non-rechargeable Battery Li-SOCl₂
- (SAV-C0011) Rechargeable Battery Li-Ion

The battery operating life and performance depends on the type of battery, actual usage and environmental factors.



DATA ON BATTERY GIVEN IN THIS MANUAL ARE INTENDED FOR A NEW AND FULLY CHARGED BATTERY WITH CONSTANT TEMPERATURE AT 20°C AND 45% OF RELATIVE HUMIDITY WITHOUT CONDENSATION.

Non-rechargeable battery (SAV-C0903)

The non-rechargeable battery is supplied fully charged and ready for use.

It's designed to have a long life and does not require any maintenance.

Estimated Shelf Life (from date of manufacture): 8 years when stored in its original packaging

Estimated Standby Life (from date of installation): 5 years once connected to AED, assuming one battery insertion test (AED activation) and daily self-tests but without using the AED in a rescue



SHELF LIFE IS DEFINED AS THE LENGTH OF TIME A BATTERY CAN BE STORED, PRIOR TO INSTALLATION INTO AED, WITHOUT DEGRADING ITS PERFORMANCE. STORING THE BATTERY OUTSIDE THE TEMPERATURE RANGE GIVEN IN THIS MANUAL WILL DECREASE BATTERY LIFE.



STANDBY LIFE IS DEFINED AS THE LENGTH OF TIME A BATTERY, ONCE INSTALLED TO AED, WILL POWER THE AED ONLY FOR CONDUCTING ITS ROUTINE DAILY SELF-TESTS BUT NOT FOR USING THE AED IN A RESCUE. KEEPING AED WITH ITS BATTERY OUTSIDE THE TEMPERATURE RANGE GIVEN IN THIS MANUAL WILL DECREASE BATTERY LIFE.

This battery is able to perform a high number of shocks that vary according to the model and versions:

SAVER ONE

- Standard 200J: 300 complete cycles (shocks at 200J and CPR) or 35 hours ECG Monitoring
- Power 360J: 200 complete cycles (shocks at 360J and CPR) or 35 hours ECG Monitoring

SAVER ONE D and SAVER ONE P

- Standard 200J: 250 complete cycles (shocks at 200J and CPR) or 24 hours ECG Monitoring
- Power 360J: 160 complete cycles (shocks at 360J and CPR) or 24 hours ECG Monitoring

Rechargeable battery (SAV-C0011)

The rechargeable battery is supplied fully charged and ready for use.

It's designed to have a long life but needs to be recharged with the dedicated charger (SAV-C0012) and related accessories supplied by A.M.I. Italia Srl.

This battery is able to perform a high number of shocks that vary according to the model and versions:

SAVER ONE

- Standard 200J: 250 shocks at 200J or 21 hours ECG Monitoring
- Power 360J: 150 shocks at 360J or 21 hours ECG Monitoring

SAVER ONE D and SAVER ONE P

- Standard 200J: 200 shocks at 200J or 14 hours ECG Monitoring
- Power 360J: 110 shocks at 360J or 14 hours ECG Monitoring

It is advisable to replace these batteries every 2.5 years or after more than 300 charge cycles (whichever occurs first).



RECHARGE THE BATTERY AT LEAST ONCE EVERY 4 MONTHS TO ALLOW PERFECT OPERATION AND EXTEND ITS LIFE.

1.4.4 Battery Installation

The following are detailed instructions for properly installing both the type of batteries, non-rechargeable or rechargeable) in the AED.



- Place the device on the side as shown and hold it securely with the left hand. Then insert the battery in the direction of the arrow making it fit perfectly with the point indicated by the circle.
- Push the battery as shown in the direction of the arrow until you hear a click that confirms the correct insertion.

Follow below instructions to **remove** the battery:



- C. Place the device on the side as shown and hold it securely with the left hand. Then, using two fingers of the right hand press on the hook of the battery highlighted by the circle.
- D. Simultaneously pull the battery in the direction indicated by the arrow.



REMOVE THE BATTERY FROM THE DEVICE ONLY IF THE DEVICE IS TURNED OFF FOR AT LEAST 5 SECONDS. FAILURE TO DO SO, COULD SEVERELY DAMAGE THE DEVICE AND THE BATTERY.

1.4.5 Charging Station for Rechargeable Battery

The complete charging station (SAV-C0014) allows recharging the rechargeable battery (SAV-C0011).

The complete charging station is formed of the following parts:

- (SAV-C0012) Battery charger model CBACCS1
- (SAV-C0013) Power supplier AC/DC Adapter P66A-3P2JA Meanwell model
- (SAV-C0366) Power cord



The CBACCS1 charger is structured as follows:



No.	Description	Function
1	Recharge LED	Indicates the battery power, or the functional status of the battery charger
2	Supply	Inlet for connecting the power supplier 12V, 5A
3	Battery contacts	Contacts for exchange of energy between the charger and battery

The CBACCS1 charger shall be used only with the power supplier AC/DC Adapter P66A-3P2JA Meanwell model (SAV-C0013) provided by A.M.I. Italia Srl.

The charger station has to be assembled for getting started: connect the AC/DC Adapter to the CBACCS1 charger, then connect the power cord to the AC/DC Adapter and plug it into the main power supply.

To connect/disconnect the rechargeable battery (SAV-C0011) in the charger CBACCS1 follows the instructions as it was installed to AED (see Battery Installation section).

The charging time of about 2.5 hours could increase in case of a battery that has been charging for more cycles than indicated. The CBACCS1 charger is equipped with a status LED that indicates both its functional status, as well as the battery's charge level, if inserted.

Below is a table that allows identifying the encoding of the status LED:

INDICATOR	RED		GREEN	
FIXED	Non-operational battery		Full battery charge	
FLASHING	Inserted battery	Charger failure	Inserted battery	Battery charging
	Non-inserted battery		Non-inserted battery	Charger waiting for battery insertion

When charging, the status LED of the charger will flash green with different frequencies depending on the charging level until full charge indicated by the status LED with FIXED green light.



Charging level	0%	25%	50%	75%	100%
Number of consecutive flashes	1	2	3	4	Fixed

1.4.6 Defibrillation Pads Options

The AED allows using two different defibrillation pads according to the patient's needs:

- (SAV-C0846) Adult defibrillation pads
- (SAV-C0016) Paediatric defibrillation pads

The defibrillation pads come in a sealed package containing one pair of pre-gelled self-adhesive pads with an attached cable and a special anti-shock safety connector to be plugged to AED.

The pads are disposable and should be discarded after each rescue.

The pads have a limited shelf life and should not be used beyond the expiration date (typically 30 months).

Keep a fresh, unopened pair of pads into the AED at all times.

Refer to the pad package label for operation temperatures.

They are polarized, meaning, the positioning of the electrodes **must not be reversed**. Improper placement of the electrodes may distort the reading of the patient's heart rate.



USING PADS THAT ARE DAMAGED OR EXPIRED MAY RESULT IN IMPROPER AED PERFORMANCE.

PADS ARE FOR SHORT TERM USE ONLY. DO NOT OPEN UNTIL READY TO USE.

Defibrillation Pads for Adults (SAV-C0846)

They shall be used on adult patients (**age >8 years or weighing >25Kg**).

Defibrillation Pads for Children (SAV-C0016)

They shall be used only on children (**age <8 years or weighing <25Kg**).

This defibrillation pads allow giving shocks to paediatric patients with reduced energy level equal to 50J.

Device senses when these type of pads are installed and adjusts to use a more appropriate lower energy level.

1.4.7 Automatic Self-Tests

The AED is designed to be completely safe, always ready for use and requires little maintenance. In fact, thanks to a sophisticated software system it is able to automatically and continuously verify if the device is able to function properly. The AED is able to automatically perform tests in different ways:

- **Activation:** Whenever you insert a battery in the device
- **Start-Up:** When switching on the device
- **Daily Routine:** During the standby mode on a daily/monthly/semi-annual basis

Activation Test

Each time a battery, new or replaced, is installed the device will perform a diagnostic activation test.

Once the battery is connected the device automatically turns on activating the following voice instruction:

Voice message: *Device test*
 Press shock button

The test is performed automatically but to verify the functionality of the buttons on the keyboard is required the assistance of the operator. The shock button will light up with flashing lights and then the operator will have maximum 1 minute to press the shock button.



IF THE SHOCK BUTTON IS NOT PRESSED WITHIN 1 MINUTE (TIME LIMIT), THE DEVICE SHALL DISPLAY AN ERROR.

SWITCH ON THE DEVICE AGAIN AND PRESS THE SHOCK BUTTON WITHIN THE TIME LIMIT INDICATED.

HOWEVER, IF THE SHOCK BUTTON IS PRESSED BUT CONTINUES TO FLASH, THEN IT MEANS THAT THE SHOCK BUTTON IS NOT WORKING PROPERLY. TURN OFF THE DEVICE AND PERFORM THE OPERATION AGAIN, IF THE PROBLEM PERSISTS, CONTACT YOUR AUTHORIZED SERVICE CENTRE.

If the shock button is pressed properly it will stop flashing and the device will start the activation test.

During this test, the device makes a complete check (firmware/hardware) that considerably drains the battery therefore we recommend to never disconnect it from the device.

Turn off the device if not to be used immediately and leave the battery in place to ensure the execution of periodic self-testing.

Start-Up Test

This test is performed automatically and takes a few seconds in order to verify the correct operation of the device before the use.

After pressing the ON/OFF button, the device will beep as it powers up, the status LED will switch off and the AED will prompt:

Voice message: *Device test*
Text displayed: START-UP TEST IN PROGRESS
 TEST SUCCEEDED

From this moment the device is ready for use and shall provide the operator with the first instructions to start the rescue.

Daily Routine Test

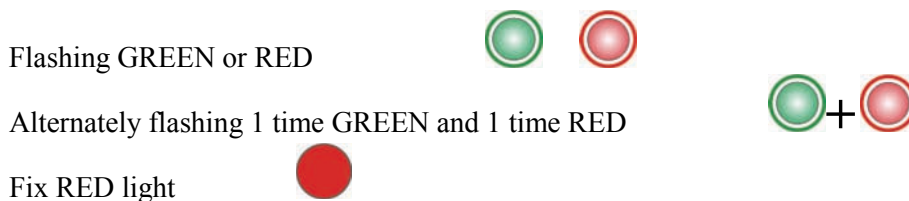
This test is performed automatically in standby mode (device turned off with battery installed) everyday at the same time set at the factory (typically during the night).

When performing the daily self-tests the AED automatically turns ON and the ON/OFF button lights up; performs the self-test for a few seconds and if successful, the Status LED Indicator reverts to GREEN FLASHING and the device turns itself OFF.

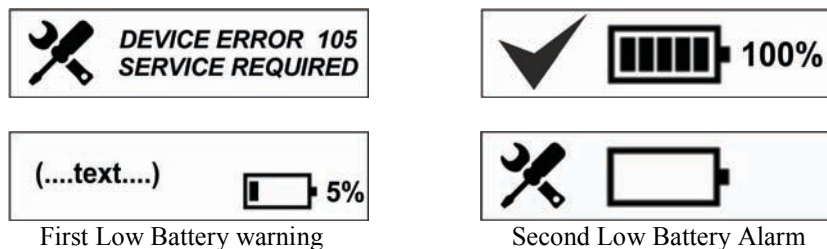
1.4.8 AED Indicators

The results of the self-test can be viewed via a bi-colour (green/red) STATUS LED INDICATOR and prompts on the LCD MINI-DISPLAY. Both are located on the front of the device and, based on the information given the operator can establish the functional status of the device and its battery.

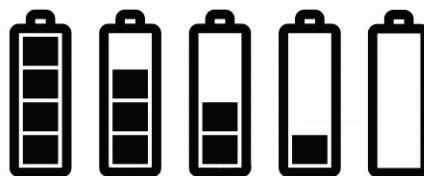
The STATUS LED INDICATOR may show various lighting combination with green and/or red colour.



The LCD MINI-DISPLAY may show TEXT WITH ERROR CODE for service and/or a BATTERY GAUGE INDICATOR.



The battery gauge indicator has 5 levels of degradation. With the use of the AED, the Battery Gauge Indicator will gradually go down from right to left as the battery capacity decreases.



There are two alarm thresholds informing the user when the power of the battery is low.

In Operating Mode, a voice message and displayed prompt:

- 1st warning with a $\leq 5\%$ battery level only when the device is operating.
In this case the AED is able to carry out about 14 shocks or 40 days in standby mode.

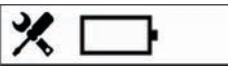
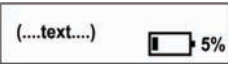
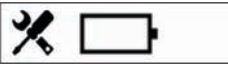
Voice message: *The battery is getting low*
Prompt displayed: The battery gauge indicator at 5% next to standard operating text

In Standby and Operating Mode a voice message and displayed prompt:

- 2nd alarm with a $\leq 1\%$ battery level when the device is in standby or operating.
In this case the AED is able to carry out about 7 shocks or 20 days in standby mode (with this condition it is not advisable to use the device).

Voice message: *Low battery. Replace the battery*
Prompt displayed: An empty battery gauge indicator next to a wrench for service icon

The following table shows the coding of the flashing STATUS LED INDICATOR and prompts displayed on the LCD Mini-Display:

AED Mode		Status LED	Mini Display
STANDBY	AED is ready for use		
	Second alarm for low battery level <1% (battery should be replaced)	 	
	AED has an error (service required)		
OPERATING	AED functioning	OFF	Standard Operations.....
	First warning for low battery level <5% AED will prompt “Battery is getting low” (battery should be replaced as soon as possible)	OFF	
	Second alarm for low battery level <1% AED will prompt “Low battery. Replace battery” (battery should be replaced immediately)		

1.4.9 Voice Prompts

The voice prompts activate when the AED is turned on and help guide the operator through the rescue. The following table lists the voice messages and a description of when the prompts are issued.

Voice Prompt	Situation
<i>Device Test</i>	Plays after turning on the AED as self-test
<i>Stay calm and follow these voice instructions</i> <i>Call the Emergency Services now!</i>	Initial instructions
<i>If the patient is unresponsive and is not breathing</i> <i>Loosen or remove clothing to expose the bare chest and apply the electrodes</i>	Prompts the rescuer to remove patient clothing in order to expose the bare chest and apply the pads.
<i>Open the package and look carefully at the picture on the electrodes</i> <i>Peel electrodes from plastic liner</i>	Prompts the rescuer to open pads package before applying to patient chest.
<i>Place the two electrodes firmly to bare chest as shown in the picture</i>	Repeats every 2 seconds until the defibrillation pads are well connected to patient and device.
<i>Do not touch patient! Analysing heart rhythm</i>	Prompts during the analysis of the patient’s cardiac rhythm and repeats until is completed.
<i>Shockable rhythm detected</i>	Prompts the rescuer AED detected a cardiac rhythm where a shock is needed
<i>Stay clear of patient! Charging for the shock</i>	AED is preparing for the shock and repeats until is ready to shock

<i>Press shock button</i>	Prompts after the AED Semi-Automatic is fully charged and ready to deliver the shock. The SHOCK button flashes and the prompt repeats for 18 seconds or until the SHOCK button is pushed.
<i>Caution. The shock will be delivered automatically in 5 seconds</i>	Prompts after the AED Fully Automatic is fully charged and ready to deliver an automatic shock. The SHOCK light flashes and the SHOCK will automatically be administered approximately five seconds after the end of the voice prompt. Time is marked by 5 beep sound.
<i>Shock delivered</i>	Prompts when the shock is delivered
<i>It is safe to touch the patient. Begin Cardio Pulmonary Resuscitation, now Make 5 cycles of 30 chest compressions followed by 2 rescue breaths</i>	Advises the rescuer that it is safe to touch the patient and have to perform CPR: • After the AED delivers a shock. • After the AED detects a non-shockable rhythm.
<i>Press patient's chest down fast</i>	Prompts the rescuer to press down one third depth of patient's chest (from 5 to 6 centimetres). A built-in metronome assist rescuer providing audio cues for the appropriate number and rate of chest compressions (30 times at 100/minute).
<i>Give 2 rescue breaths</i>	Prompts to give two breaths to patient.
<i>Blow</i>	Prompts to give the first breath
<i>Blow</i>	Prompts to give the second breath
<i>No shock advised</i>	Prompts the rescuer that no shock is needed.
<i>The battery is getting low</i>	Warns for the first time a low battery level $\leq 5\%$
<i>Low battery Replace the battery</i>	Alarms for a discharged battery level $\leq 1\%$ when the rescuer should replace the battery.
<i>Shock Cancelled. Shock button not pressed</i>	When the device is ready to shock but the user has not pressed the shock button (Semi-Automatic AED) therefore the device cancels the shock and disarms itself.
<i>Shock Cancelled. Rhythm changed</i>	When the device is prepared to shock then detects a change in rhythm and therefore cancels the shock and disarms itself.
<i>Device failed. Service required</i>	Occurs after the self-test determine that the AED is not functioning properly. The prompt will be heard when the device is turned ON and will repeat until is turned OFF.
<i>Paediatric Mode</i>	Occurs when paediatric pads are installed to AED.

1.5 INSTRUCTIONS FOR USE

This section provides information about how to use the AED to perform a rescue.

1.5.1 Chain of Survival

ERC (European Resuscitation Council) and the AHA (American Heart Association) have established a protocol with sequence of rescue actions to be observed during the resuscitation of a person suffering from sudden cardiac arrest. This protocol is called the "chain of survival".



1. Make sure that the victim needs aid (no signs of circulation) and call EMS immediately
2. While waiting for a defibrillator to become available, immediately start CPR
3. Use the AED to restore the normal heart rhythm
4. Post resuscitation care by ALS personnel

1.5.2 Patient Preparation

Determine that the patient is over 8 years of age or weighs more than 25 kg and is both:

- Unresponsive
- Not breathing

As soon as the AED is available for the rescue turn it on and follow the instructions.

The AED will prompt:

- *Stay calm and follow these voice instructions*
- *Call Emergency Services now*
- *If the patient is unresponsive and is not breathing*
- *Loosen or remove clothing to expose the bare chest and apply the electrodes*

Remove or cut clothing (if needed) from the patient's chest. If the patient's chest has a thick hair it is necessary to shave it in the places where the Pads shall be placed.



WHEN THE PATIENT IS A CHILD UNDER 8 YEARS OF AGE OR WEIGHS LESS THAN 25KG. THE AED SHOULD BE USED WITH THE SAV-C0016 PAEDIATRIC DEFIBRILLATION PADS. THERAPY SHOULD NOT BE DELAYED TO DETERMINE THE PATIENT'S EXACT AGE OR WEIGHT.

1.5.3 Place Defibrillation Pads

The AED will prompt "*Open the package and look carefully at the picture on the electrodes*"

Remove the defibrillation PADS from the package.



If you are using not pre-connected defibrillation pads or paediatric pads, plug the pads connector to AED.



The AED will prompt *“Peel electrodes from plastic liner. Place the two electrodes firmly to bare chest as shown in the picture”*

Remove the protective film from each pad and place both defibrillation pads on the patient's chest as shown on the picture.



The defibrillation PADS are polarized, and require to be positioned at the points indicated by the picture given on each pad. When the patient is a child use the SAV-C0016 paediatric defibrillation pads.

The correct placement of the pads is essential for the efficient analysis of the patient's heart rate and the subsequent shock delivery (if needed).

1.5.4 Heart Rate Analysis

When the pads are placed the AED will prompt *“Do Not Touch Patient. Analysing Heart Rhythm”*

The AED will automatically begin to analyse the cardiac rhythm of the patient.

If, during the analysis, the pads become disconnected from the AED, the prompt *“Place the two electrodes firmly to bare chest as shown in the picture”* will be heard.

If this occurs, check to be sure the connector is properly plugged into the AED and that pads are firmly placed on clean, dry skin.

During the analysis, the body of the patient should not be touched and should not be subjected to vibration or movement.

1.5.5 Shock Delivery

If a shock is advised the AED will prompt *“Shockable rhythm detected. Stay clear of patient. Charging for the shock”* and rescuer should ensure that no one is touching the patient.

When the AED is fully charged ready to deliver a defibrillation shock:

- A. The SEMI-AUTOMATIC AED will flash the shock button and the prompt *“Press shock button”* will be heard. Make sure no one is touching the patient and press the shock button to deliver a defibrillation shock. If the shock button is not pressed within 18 seconds of hearing the prompt, the AED will disarm with the voice prompt *“Shock cancelled. Shock button not pressed”*. Then will prompt to start CPR.
- B. The FULLY AUTOMATIC AED will light up a shock icon and the prompt *“Caution! The shock will be delivered automatically in 5 seconds”* will be heard. Make sure no one is touching the patient because the device will deliver the defibrillation shock after 5 beep sounds.

For both models, after the AED delivers the defibrillation shock, the voice prompt will say *“Shock Delivered”* and prompt to start CPR.

When the AED is charged, it continues to analyse the patient's heart rhythm and in case the rhythm changes and a shock is no longer needed, the AED will prompt the message *“Shock cancelled. Rhythm changed”* and prompt to start CPR.

If during the analysis the AED does not detect shockable rhythm (VF or VT) the defibrillation shock is not needed and the AED will prompt *“No shock advised”*. Then will prompt to start CPR.

1.5.6 CPR

The AED will guide rescuer through all steps of CPR (Cardio Pulmonary Resuscitation) and will prompt *“It is safe to touch the patient. Begin Cardio Pulmonary Resuscitation, now. Make 5 cycles of 30 chest compressions followed by 2 rescue breaths”*

Kneel by the side of patient and prepare to make compressions as follows:

1. Place the heel of one hand on the centre of the chest, between nipples
2. Place the heel of the other hand directly on top of first hand
3. Lean over patient with elbows straight
4. Press the patient's chest down rapidly one third depth of chest ensuring that pressure is not applied on the victim's ribs



The AED will prompt *“Press patient's chest down fast”*

Press down on the sternum 5-6 cm. Then, release the pressure without losing contact between your hands and the sternum. Repeat at a rate of 100 compressions per minute. Compression and release should take the same time.

The metronome will provide audio cues for the appropriate number and rate of chest compressions.

After 30 compressions the AED will prompt *“Give 2 rescue breaths”*

Close the nose pinching its soft part using the index finger and thumb of your hand on the forehead. Maintaining chin lift allows the mouth to open, take a normal breath and place your lips around his mouth.	
Blow steadily into the mouth while watching for the chest to rise (take about 1 second as in normal breathing). Move your mouth away, take other normal breath and blow into the mouth once more, to achieve a total of two effective rescue breaths. The AED will prompt <i>“blow”</i> twice.	

This cycle will continue until the CPR time expires (about 2 minutes).
At the end of CPR the AED will return analysing the heart rhythm.

If the patient is conscious and breathing normally, leave the pads on the patient's chest connected to the AED. Make the patient as comfortable as possible and wait for Advanced Life Support (ALS) personnel to arrive.

Continue to follow the voice prompts until the ALS personnel arrive.

1.5.7 Post Rescue

After transferring the patient to ALS personnel, prepare the AED for the next rescue:

1. Check the remaining capacity of the memory card or, if required, retrieve the rescue data stored in the AED (see Data Management section).
2. Connect a new pair of pads to the AED
3. Verify the remaining capacity of the battery
4. Verify that the Status LED Indicator is flashing green.

1.6 DATA MANAGEMENT

The AED is designed for ease of data management and review.

The AED is able to record and store both the **SERVICE data** as well as the **RESCUE data** (full details of the rescue operations performed).

The recording and storing of data occurs automatically (cannot be disabled by the user) on the **internal memory** of the device as well as on a **removable memory Card** when installed.

The data stored can be displayed on the PC screen using the dedicated data management software SAVER VIEW EXPRESS.

1.6.1 Rescue Data

The AED can store up to 6 hours of rescue data (audio, ECG and events) in the device's internal memory. Multiple rescues can be stored in the internal memory, allowing the rescuer to administer additional rescues without downloading the data to a PC.

Each rescue session generate a file saved as “nnnnnnXX.aed” where the first six “n” represents the current date (day-month-year) and the following two “X” are a daily progressive counts expressed with uppercase letters. Those files, called “AEDFILE” have extension “.aed” and can be reviewed only with the dedicated PC Software SAVER VIEW EXPRESS.

Should the internal memory become full, the AED will purge rescues as needed, beginning with the oldest AEDFILE.

SD Removable Cards can be used to extend AED's memory. The card must be inserted before connecting the battery into the dedicated port on the rear of the AED.



The length of storage depends on the card capacity:

- 512 MB up to 25 hours of rescue data
- 1 GB up to 50 hours of rescue data
- 2 GB up to 100 hours of rescue data
- 4 GB up to 200 hours of rescue data

Further to the rescue data (AEDFILE.aed) the AED is able to record a file named “AED1LOG.txt” able to store all automatic daily self-tests performed by the device with their result and any information needed for service. That's a simple text file that can be displayed on PC with common text software.

1.6.2 Reviewing Rescue Data

The data stored can be displayed on the PC screen, analysed and printed out, using the dedicated data management software SAVER VIEW EXPRESS (SAV-C0017).



For more details please refer to its User Manual.

1.7 MAINTENANCE AND TROUBLESHOOTING

This section presents information about the AED diagnostics self-tests, maintenance, and service indications.

1.7.1 Routine Maintenance

The AED has a comprehensive self-tests systems which automatically test the electronics; battery and high voltage circuitry. There are three types of automatic self-test:

1. The Daily Self-test checks the battery, pads, and the electronic components
2. The Monthly Self-test completes a partial charge of the high voltage electronics current in addition to the items tested in the Daily Self-test
3. The Half-Yearly Self-test, the high voltage electronics are charged to full energy

Thanks to the routine self-tests there is no need to perform any special maintenance but just visual inspection of the Status LED Indicator and of the prompts given in the LCD Mini-Display along with a visual inspection of the related accessories.

Daily Check	Monthly Check	After Use Check	Inspection
*		*	Verify that the STATUS LED INDICATOR is flashing green and the LCD MINI-DISPLAY doesn't prompt any error.
	*	*	Check the BATTERY GAUGE INDICATOR.
	*	*	Verify that the EXPIRATION DATE of the ELECTRODES is still valid.
	*	*	Check the INTEGRITY of the AED CASE.
		*	Check the capacity of the MEMORY CARD (if installed).

1.7.2 Troubleshooting Guide

The following table lists the symptoms, possible causes and possible corrective actions for problems that may arise. For further clarification about the implementation of corrective actions, refer to the other sections of the operator's manual. If the AED continues to give errors, contact Service Assistance.

STORE	The device DOES NOT SWITCH ON and both the Status Led Indicator and the LCD Mini-Display are OFF.
<i>Cause/Remedy a)</i>	The battery is totally discharged or damaged. Replace the battery. If the problem persists contact the Service Centre.
<i>b)</i>	The device does not work. Contact the Service Centre.
STANDBY	The Status LED Indicator flashes green but the Mini-Display is OFF.
<i>Cause/Remedy:</i>	The LCD Mini-Display is damaged. Contact the Service Centre.
STANDBY	The Status LED Indicator is OFF but the LCD Mini-Display is operating and gives prompts.
<i>Cause/Remedy:</i>	The Status LED Indicator is damaged. Contact the Service Centre.
STANDBY	The Status LED Indicator flashes RED and a WRENCH for SERVICE ICON with an ERROR CODE appears on the LCD Mini-Display.
<i>Cause/Remedy:</i>	An error occurred during the daily self-test. Contact the Service Centre and provide the error code displayed.

STANDBY	The Status LED Indicator flashes alternatively GREEN and RED; a WRENCH for SERVICE ICON is shown on the LCD Mini-Display together with an EMPTY BATTERY GAUGE INDICATOR.
<i>Cause/Remedy:</i>	Low Battery warning. The level of the battery is <1%. The device may turn off during the use. Replace the battery.
OPERATING	The prompt “ <i>The battery is getting low</i> ” is heard and the LCD Mini-Display will show a BATTERY GAUGE INDICATOR 5%.
<i>Cause/Remedy:</i>	First warning for Low Battery. The level of the battery is <5%. The battery is running low. It is possible to use the AED but replace the battery as soon as possible.
OPERATING	The prompt “ <i>Low battery. Replace the battery</i> ” is heard; the Status LED Indicator flashes RED and the LCD Mini-Display will show a WRENCH for SERVICE ICON and an EMPTY BATTERY GAUGE INDICATOR 1%.
<i>Cause/Remedy:</i>	Second alarm for Low Battery. The level of the battery is <1%. The device may turn off during the use. Replace the battery.
OPERATING	Everything seems to be ok but NO VOICE IS HEARD.
<i>Cause/Remedy:</i>	Device’s speaker doesn’t work. Contact the Service Centre.
OPERATING	Once switched on and after positioning the pads on the patient, AED continues to prompt “ <i>Place the two electrodes firmly to bare chest as shown in the picture</i> ”.
<i>Cause/Remedy a):</i>	The Pads connector is not inserted correctly in the AED or has removed. Plug the connector into the proper port.
b)	The Pads have been positioned incorrectly. Properly place the pads on the patient's bare chest. If necessary, remove the hair from the chest with a razor.
c)	The Pads are damaged. Check the integrity and the expiration date of the pads, replace them if necessary.
ACTIVATION	After installing the battery and pressing the Shock button as requested by the device for the activation test, the START-UP TEST DOES NOT PROGRESS and the LCD Mini-Display will show a WRENCH for SERVICE ICON with an ERROR CODE.
<i>Cause/Remedy:</i>	The Shock button does not work properly. Try switching off the device and repeat the activation test. If the problem persists contact the Service Centre.

1.7.3 Authorized Repair Service

The AED has no user-serviceable internal components. Try to resolve any maintenance issues with the AED by using the Troubleshooting Guide presented in the previous section. If you are unable to resolve the problem, contact A.M.I. Italia Srl Customer Service or contact the local SAVER ONE distributor.



SHOCK HAZARD! DO NOT DISASSEMBLE THE AED. FAILURE TO OBSERVE THIS WARNING CAN RESULT IN PERSONAL INJURY OR DEATH. REFER MAINTENANCE ISSUES TO A.M.I. ITALIA AUTHORIZED SERVICE PERSONNEL.

1.7.4 Cleaning

The structure of the device, including the connection port of the defibrillation parts, can be sanitized by using a soft cloth moistened with one of the cleaning solutions listed below:

- A. Isopropyl alcohol (70% solution)
- B. Soapy water
- C. Bleach (30 ml per litre of water)
- D. Detergents containing ammonia
- E. Detergents containing glutaraldehyde

F. Hydrogen peroxide



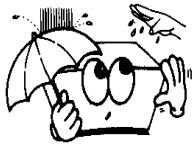
DO NOT IMMERSE THE AED IN ANY LIQUID.

DO NOT USE ABRASIVE MATERIALS, CLEANERS, STRONG SOLVENTS SUCH AS ACETONE OR ACETONE-BASED DETERGENTS, AND ENZYMATIC CLEANERS.

DO NOT STERILIZE THE AED OR ITS ACCESSORIES.

1.7.5 Storing

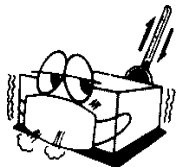
The AED should be installed in a place where the environmental and safety conditions in the table below are observed. When installed it is advisable to store the device with battery inserted to allow the device to perform the routine self-testing operations. For easy retrieval of the device in case of emergency, place it in a location that is easily accessible and oriented so that the Status LED Indicators are sufficiently prominent.



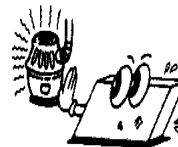
Do not use, install, or maintain AED in conditions of temperature or humidity that exceed the range given in this user manual.



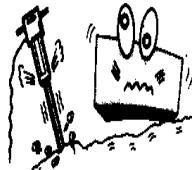
Do not install or store the AED in areas directly exposed to sun light.



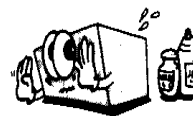
Do not install or store the AED in areas subject to extreme changes in temperature or humidity.



Do not install or store the AED near sources of heat.



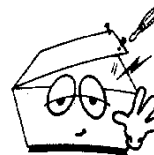
Do not use, install or store the AED in locations subject to strong vibration.



Do not use, install or store the AED in environments with high concentrations of flammable gases or anaesthetics.



Do not install or store the AED in areas with high dust concentration.



The AED shall be opened for maintenance only by A.M.I. Italia Srl or persons authorized by the company.



EXPOSING THE AED TO EXTREME ENVIRONMENTAL CONDITIONS OUTSIDE OF ITS OPERATING PARAMETERS MAY COMPROMISE THE ABILITY OF THE AED TO FUNCTION PROPERLY.

1.8 TECHNICAL DATA

This section lists the AED and some Accessories parameters.

	SAVER ONE		SAVER ONE D	SAVER ONE P
	SVO-B0001 SVO-B0002	SVO-B0847 SVO-B0848	SVD-B0004 SVD-B0005	SVP-B0006 SVP-B0007
DEVICE				
Size (W x D x H)	26,5 x 21,5 x 7,5 cm			
Weight w/disposable battery	1,95 kg		2,30 kg	
Weight w/rechargeable battery	2,10 kg		2,45 kg	
Battery Option	➤ Li-SOCl ₂ Non-Rechargeable Battery(SAV-C0903) ➤ Li-Ion Rechargeable Battery (SAV-C0011)			
Device Classification	Class IIb according to Directive 2007/47/EC			
Defibrillation Pads	Adult (SAV-C0846) and Pediatric (SAV-C0016)			
Recording	1Gbit (128 MB) Internal Memory and Removable SD Memory Cards			
Data Transfer	2.0 mini USB (USB/Mini USB) and IrDA Port (option)			
ENVIRONMENT				
Operating Temperature	0°to +55° C			
Storage Temperature	-35°to +65° C			
Humidity	0 to 95% relative humidity non-condensing			
Shock / Drop resistance	Conform to EN 60601-1Clause 21			
Dustproof/Waterproof Protection	Class IP54 according to IEC 60529			
Electrostatic Shocks	Conform to the EN 61000-4-2, security level 4			
Electromagnetic Interference (Radiation)	Conform to EN 60601-1-2, method EN 55011, group 1 level B			
Electromagnetic Interference (Protection)	Conform to EN 60601-1-2, method EN 61000-4-3, level 2			
DEFIBRILLATOR				
Waveform	Adaptive BTE (Biphasic Truncated Exponential)			
Patient Safety	All patient connections are electrically completely isolated			
Operation	Semi-Automatic	Fully-Automatic	Semi-Automatic	➤ Semi-Automatic ➤ Manual
Energy Type	Escalating from 50 to 360J			
Energy Selection	Automated (pre-programmed)			➤ Automated ➤ Manual
Automated Adult Shock Sequence	Standard Version:		150, 200, 200J (50 Ω load)	
	Power Version:		200, 250, 360J (50 Ω load)	
Automated Child Shock Sequence	Standard/Power Version:		50J fixed (using pediatric pads SAV-C0016)	
Manual Shock Sequence	---			From 50J to 360J (50 at time)
Accuracy	± 15%			
Charging Time (from Shock notice) IEC60601-2-4 §6.8.2 (7a)	≤ 9 seconds (Standard Version) with new and fully charged battery ≤ 15 seconds (Power Version) with new and fully charged battery			
Charging Time (from Start of Analysis) IEC60601-2-4 §6.8.2 (8a)	≤ 15 seconds (Standard Version) with new and fully charged battery ≤ 21 seconds (Power Version) with new and fully charged battery			

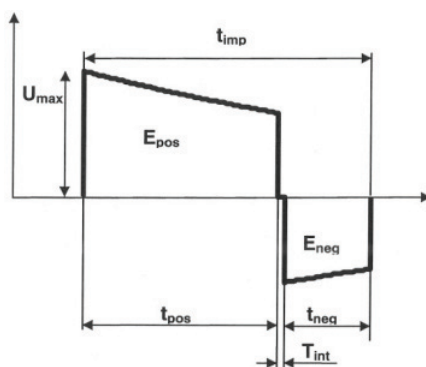
		SAVER ONE		SAVER ONE D	SAVER ONE P
		SVO-B0001 SVO-B0002	SVO-B0847 SVO-B0848	SVD-B0004 SVD-B0005	SVP-B0006 SVP-B0007
DEFIBRILLATOR (continued)					
Defibrillator Disarm	➤ Heart rhythm changed in a non-shockable one, or ➤ Shock button non pressed within 18 seconds (except Fully Automatic), or ➤ ON/OFF button pressed, or ➤ Pads disconnected. or ➤ Battery removed				
Patient Isolation	BF Type				
Automatic Self-Test	➤ Each time the device is turned on, and ➤ Daily / Monthly / 6 Months, and ➤ Each time a battery (new or replaced) is attached to device				
CPR	Instructions and audio cues with a metronome for the appropriate number and rate of chest compressions (100 per minute)				
Electrode Patient Impedance Measurement Range	20 to 200 ohms				
Defibrillator Electrode ECG Circuitry	Protected				
Algorithm	Arrhythmia detector that evaluates chest’s impedance and determines if shock is required				
Shockable Rhythms	Ventricular Fibrillation (VF) and wide complex Ventricular Tachycardia (VT)				
Sensitivity	97% as per EN 60602-2-4 (AHADB, MITDB source)				
Specificity	99% as per EN 60602-2-4 (AHADB, MITDB source)				
BATTERY					
Non-Rechargeable Battery	Li-SOCl ₂ (Lithium-thionyl chloride) to lose, non-refillable (SAV-C0903)				
Voltage	25,2 VDC – 3500 mAh				
SAV-C0903 Capacity (typical new battery at 20° C)	Standby life (installed to the device)5 years, or				
	300 rescue cycles (shocks at 200J and CPR) or 200 rescue cycles (shocks at 360J and CPR) or 35 hours ECG Monitoring	250 rescue cycles (shocks at 200J and CPR) or 160 rescue cycles (shocks at 360J and CPR) or 24 hours ECG Monitoring			
Rechargeable Battery	Li-Ion (ion battery) Rechargeable (SAV-C0011)				
Voltage	21,6 VDC - 2100 mAh				
Shelf-Life	2.5 years or 300 charge/shock cycles (whichever occurs first)				
Charging Time	≤ 2,5 hours (only with SAV-C0014 charging station)				
SAV-C0011 Capacity (typical new battery at 20° C)	250 shocks at 200J or 150 shocks at 360J or 21 hours in ECG Monitoring	200 shocks at 200J or 110 shocks at 360J or 14 hours in ECG Monitoring			
	Shelf-Life: 2,5 years or 300 charging cycles				

	SAVER ONE		SAVER ONE D	SAVER ONE P
	SVO-B0001 SVO-B0002	SVO-B0847 SVO-B0848	SVD-B0004 SVD-B0005	SVP-B0006 SVP-B0007
CHARGER				
Model	CBACCS1 (SAV-C0012)			
Inlet	12 VDC – 5A			
Outlet	26VDC – 1,5A			
Absorption	40W			
AC/DC ADAPTER FOR CBACCS1				
Model	Meanwell P66A-3P2J (SAV-C0013)			
Inlet	100-240VAC – 50/60Hz – 1.5A			
Outlet	12V – 5.5°			
Absorption	66W			
DEFIBRILLATION PADS				
Type	Disposable, Self-Adhesive and Pre-Gelled			
Tolerance to Shocks	50 shocks at 360J			
Support Material	Medical FOAM. Thickness 1mm			
Conductive Gel	Low impedance conductive adhesive gel			
Conductive Material	Metal Sheet			
Connector Type	Anti-shock safety connector			
Cable Length	120cm			
Adult Pads	Pre-Connected (SAV-C0846)			
Indication for Use	Adult aged >8 years or weighing >25Kg			
Total Area (per pad)	148cm ²			
Active Area (per pad)	81cm ²			
Pediatric Pads	Standard (SAV-C0016)			
Indication for Use	Children aged 1-8 years or weighing <25Kg			
Total Area (per pad)	75cm ²			
Active Area (per pad)	31cm ²			

1.9 WAVEFORM

BTE (Biphasic truncated exponential)

The parameters of the waveform are regulated automatically based on the patient's impedance. In the graph to the left t_{pos} represents the duration of phase 1 (ms), t_{neg} represents the duration of phase 2 (ms), t_{int} is the delay between the phases, U_{max} denotes the peak voltage, and t_{imp} is the final voltage. In order to compensate for variations in the patient's impedance, the duration of each phase of the waveform is dynamically adjusted based on the delivered charge, as indicated in the following examples



Maximum energy set at 150J

Load resistance (Ω)	During phase 1 (msec)* t_{pos}	During phase 2 (msec)* t_{neg}	Energy delivered (J)*
25	4	6	150,6
50	6	4	150,4
75	7	3	150,2
100	7	3	150,1
125	7	3	150,1
150	7	3	150,0
175	7	3	150,0

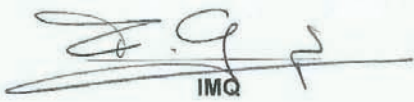
* duration $\pm 5\%$ - energy $\pm 12\%$

Maximum energy set at 360J

Load resistance (Ω)	During phase 1 (msec)* t_{pos}	During phase 2 (msec)* t_{neg}	Energy delivered (J)*
25	4	8	350,4
50	6	4	350,4
75	8	5	350,4
100	11	7	350,4
125	13	8	350,4
150	15	9	350,4
175	16	9	350,4

* duration $\pm 5\%$ - energy $\pm 12\%$

1.10 EC CERTIFICATE

EC CERTIFICATE	
Certificate No 1104/MDD	
Full Quality Assurance System Approval Certificate	
On the basis of our examination carried out according to Annex II of the Directive 93/42/EEC and its revised version, we hereby certify that:	
A.M.I. ITALIA SRL	
80121 NAPOLI (NA) - VIA DEI FIORENTINI 21 (ITA) - Italy	
manages in the factories of:	
80010 QUARTO (NA) - VIA CUPA REGINELLA 17/A (ITA) - Italy	
a full quality assurance system ensuring the conformity of the following products:	
Semiautomatic and manual semiautomatic external cardiac defibrillator	
Type ref. SAVER-ONE-P; SAVER-ONE-D	
Automatic and semiautomatic external cardiac defibrillator	
Type ref. SAVER-ONE.	
with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing).	
Reference to IMQ files Nos: 10AI00006; 10AJ00117; COMEDCONMHDM110027747-01; 10EN00018.	
This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.	
Date:	2008-02-18
Updated:	2013-02-18
Substitution Date:	2011-12-14
	
This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC". In any case, it does not remain valid after 2018-02-17 (article 11, clause 11 of the Directive).	
This is a translation of the Italian text, which prevails in case of doubts	
 IMQ S.p.A. Società a socio unico I-20138 Milano - Via Quintiliano 43 - tel. 02507311(a.) - fax 0250991500 - info@imq.it - www.imq.it Rea MI 1595884 - Registro Imprese MI 12898410159 - C.F./P.I.: 12898410159 - Capitale sociale 4.000.000 euro.	

CHAPTER 2: SAVER ONE Semi Automatic & Fully Automatic



SEMI-AUTOMATIC AED



FULLY AUTOMATIC AED

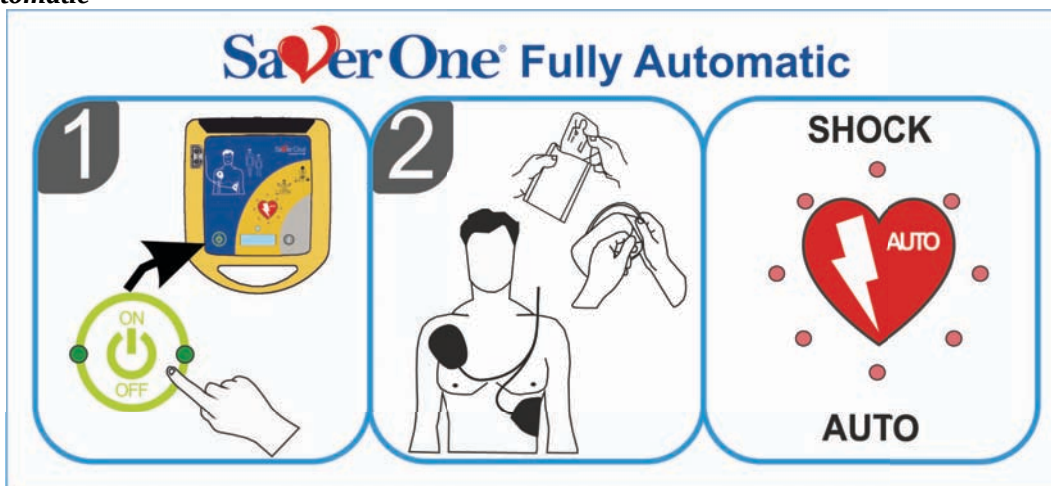
2.1 QUICK START GUIDE

This is a quick start guide included into the carry case of AED.

Semi-Automatic



Fully Automatic



2.2 STANDARD BOX CONTENTS

The **Standard Basic Configuration** (Conf-Norm) includes:

- 1 AED unit
- 1 Pair of Adult defibrillation pads
- 1 Non-Rechargeable Battery
- 1 Carrying Case (with a Quick Start Guide)
- 1 Quick Operating Guide and a User Manual

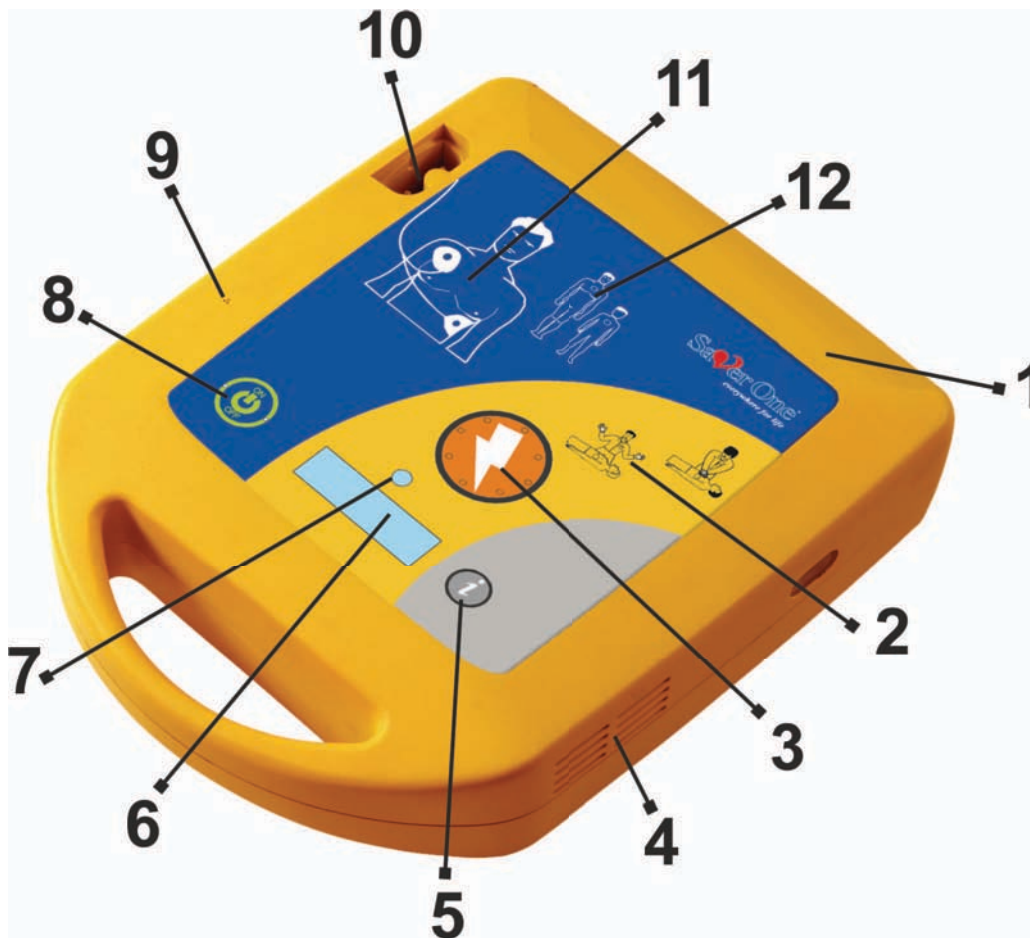
Available optional Configuration for both models:

1. Rechargeable Configuration (Conf-Rech)
(AED unit, Pair of Adult defibrillation pads, Rechargeable Battery, Charger Station, Carrying Case)

2.3 AED PARTS

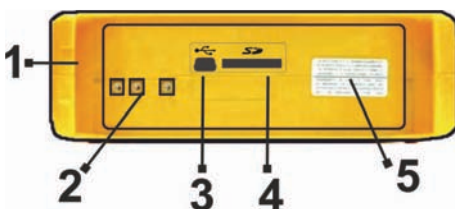
The following drawings show the AED parts and their locations.

Semi-Automatic



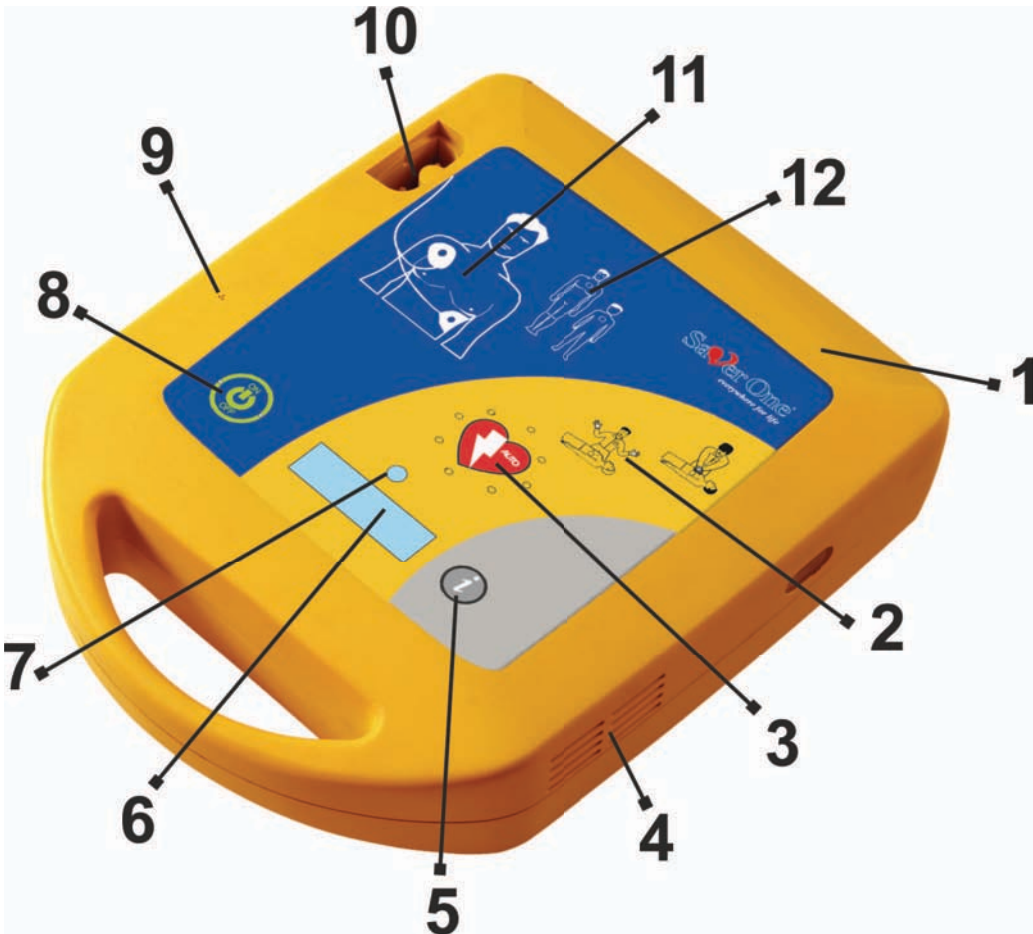
1. Battery	7. Status LED Indicator
2. Icons "Touch/Don't Touch Patient"	8. ON/OFF switch
3. Shock button	9. Microphone
4. Speaker	10. Pads or ECG cable connection port
5. "i" button	11. Icon "Place Pads"
6. LCD Mini-Display	12. Icon "Adult/Child Pads"

Rear View



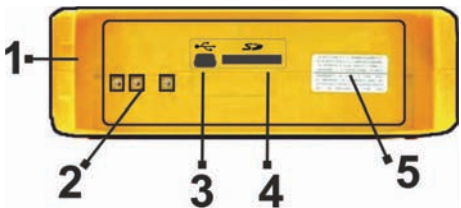
1. Battery compartment
2. Contact PINS
3. USB Port
4. Removable SD Card seat
5. Warranty seal

Fully Automatic



1. Battery	7. Status LED Indicator
2. Icons "Touch/Don't Touch Patient"	8. ON/OFF switch
3. Icon "Automatic Shock"	9. Microphone
4. Speaker	10. Pads or ECG cable connection port
5. "i" button	11. Icon "Place Pads"
6. LCD Mini-Display	12. Icon "Adult/Child Pads"

Rear View



1. Battery compartment
2. Contact PINS
3. USB Port
4. Removable SD Card seat
5. Warranty seal

2.4 AED DESCRIPTION

Saver One is designed for a public access use and licensed to administer fast and safe rescues.

Practical and intuitive, with CPR guidance and clear instructions able to support users through the whole rescue protocol for effective lifesaving actions.

Highly effective and user-friendly for any lay rescuer is able to detect and automatically analyse the victim's heart rate and capable of delivering one or more defibrillation shocks if a ventricular fibrillation (VF) or ventricular tachycardia (VT monomorphic or polymorphic with heartbeat >180) is detected.

The energy is supplied by an exponential truncated biphasic (B.T.E.) electric shock capable of self-adapting to the patient's thoracic impedance.

Saver One is available in two models:

- **Semi- Automatic** with shock button
- **Fully Automatic** able to administer a shock (if required) with no shock button for the user to press

Both **Saver One** models are available with two energy level versions:

- | | | | |
|-------------------|-------------------------------|---------------------------|-------------|
| ▪ Standard | Maximum output at 200J | Saver One Semi-Automatic | (SVO-B0001) |
| ▪ Power | Maximum output at 360J | Saver One Semi-Automatic | (SVO-B0002) |
| ▪ Standard | Maximum output at 200J | Saver One Fully Automatic | (SVO-B0847) |
| ▪ Power | Maximum output at 360J | Saver One Fully Automatic | (SVO-B0848) |

Both **Saver One** models can be used with Non-Rechargeable Battery Li-SOCl₂ (SAV-C0903) or Rechargeable Battery Li-Ion (SAV-C0011). Furthermore they can be used with Adult Defibrillation Pads (SAV-C0847) or Pediatric Pads (SAV-C0016).

2.5 TEXT SCREEN

In Operating Mode, the LCD Mini-Display of both **Saver One** models runs text prompts in tandem with audible voice instructions, helpful in noisy and chaotic environments.

The text displayed has 2 lines of multi language uppercase text prompts (text version of the voice prompts) next to the Battery Gauge Indicator.



(This example is given for a device equipped with English software.
Your AED should be equipped with the prompts in your language)

2.6 INFO BUTTON

Both **Saver One** models are equipped with a synergic **i** button.

The “INFO” button provides valuable device or battery technical information (in English) to users and is serviceable for changing the language.

The INFO button can be used only when the AED is functioning (Operating Mode) and will automatically be disabled in case of a rescue operation.

The information on the display is divided in various pages that can be scrolled by pressing the button “n” times (n is for the number of pages).

Pressing <i>First Time</i>		MODEL: ONE 200J S/N: 05ISO2213004 POWER: BATTERY	AED Model AED Serial Number Battery Type in use
Pressing <i>Second Time</i>		PROTOCOL: 150-200-200J SHOCKS: 6 DATE: 01/02/2013	Shock Protocol Number of Shock Delivered Current Date
Pressing <i>Third Time</i>		LANGUAGE - -> ITALIAN Italian English	Languages Available into AED
To change the language, keep pressing the button for about 3 seconds and then release. It will displayed:  Select the desired language by pressing the button for scrolling between those available. The choice will be black-highlighted. Therefore keep pressing the button for about 3 seconds to confirm the selection. The selected language will be kept in memory for the next AED start-up.			



SEMI-AUTOMATIC AED With ECG MONITORING

3.1 QUICK START GUIDE

This is a quick start guide included into the carry case of AED.



3.2 STANDARD BOX CONTENTS

The **Standard Basic Configuration** (Conf-Norm) includes:

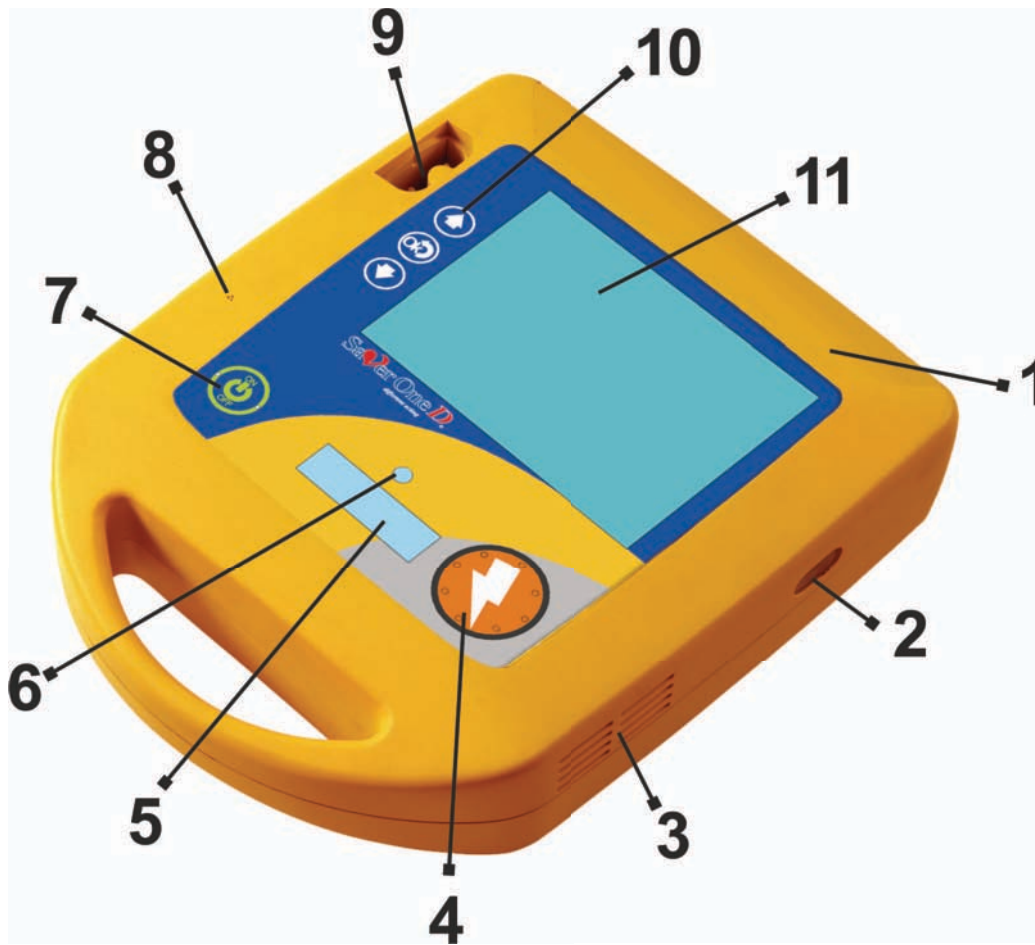
- 1 AED unit
- 1 Pair of Adult defibrillation pads
- 1 Non-Rechargeable Battery
- 1 Carrying Case (with a Quick Start Guide)
- 1 Quick Operating Guide and a User Manual

Available optional Configurations:

1. **Rechargeable Configuration** (Conf-Rech)
(AED unit, Pair of Adult defibrillation pads, Rechargeable Battery, Charger Station, Carrying Case)
2. **Print Ready Configuration** (Conf-Print)
(AED unit equipped with IrDA Port, Thermal Printer PORTI-S30, Pair of Adult defibrillation pads, Non-Rechargeable Battery, Carrying Case)
3. **Rechargeable & Print Ready Configuration**(Conf-Rech/Print)
(AED unit equipped with IrDA Port, Thermal Printer PORTI-S30, Pair of Adult defibrillation pads, Rechargeable Battery, Charger Station, Carrying Case)

3.3 AED PARTS

The following drawings show the AED parts and their locations.



1. Battery	7. ON/OFF switch
2. IrDA Port (option)	8. Microphone
3. Speaker	9. Pads or ECG cable connection port
4. Shock button	10. MENU buttons
5. Service LCD Mini-Display	11. TFT Colour screen 5.7"
6. Status LED Indicator	

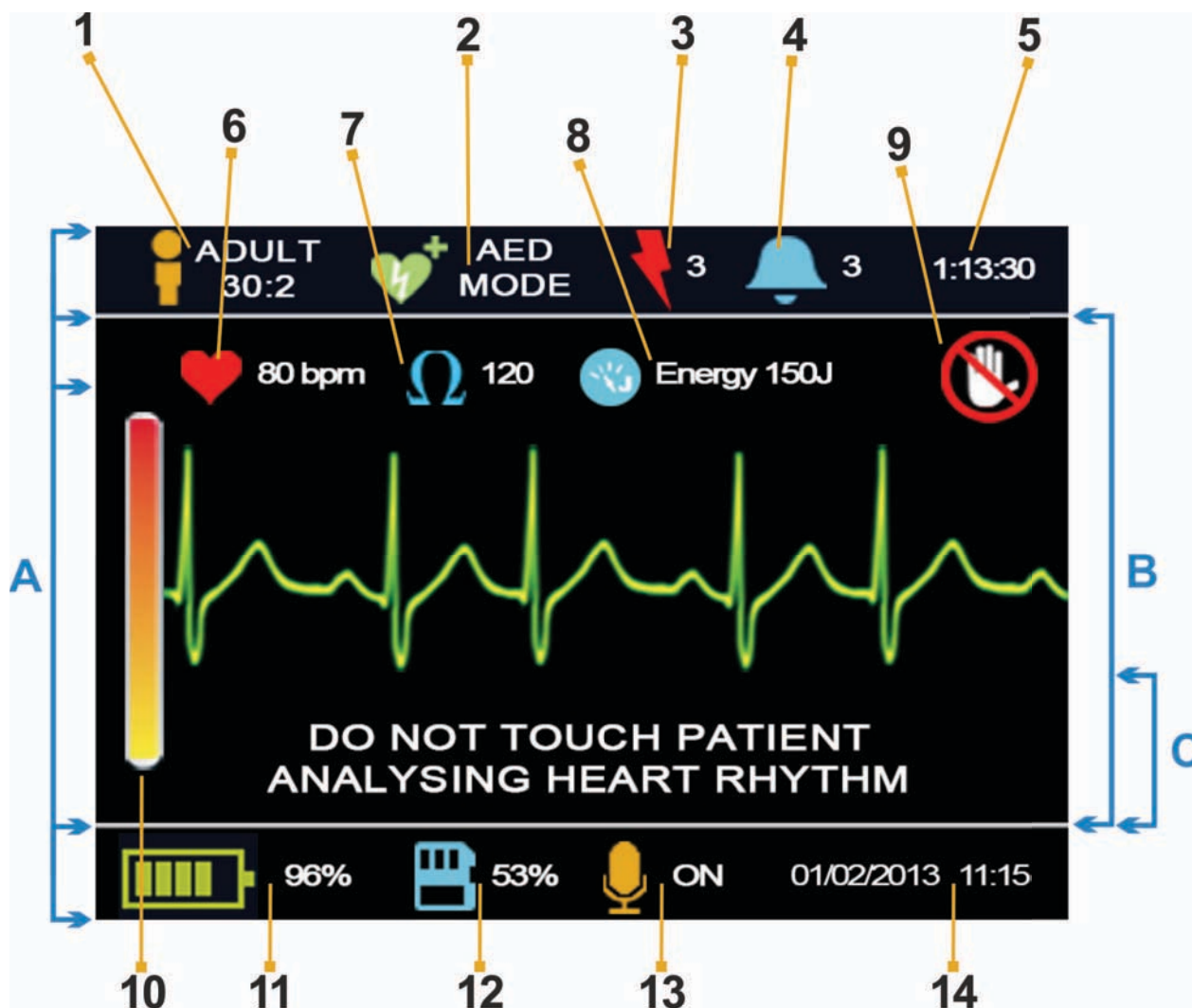
Rear View



1. Battery compartment
2. Contact PINS
3. USB Port
4. Removable SD Card seat
5. Warranty seal

3.4 TFT COLOUR DISPLAY 5.7"

The following drawings show the display equipped on *Saver One D*.



(This example is given for a device equipped with English software.
Your AED should be equipped with the prompts in your language)

A. Rescue and AED Set-Up Information Field
B. Graphic Area active during rescue.
C. Text Area running during rescue

1. Protocol (AD/PED) and CPR Ratio in use	8. Energy Level to Deliver
2. Modality (AED/ECG/SYNC/ASYN) in use	9. Icon Don't Touch Patient
3. Shock Counts	10. Charging Bar (progressing)
4. Fibrillation Alarm Counts	11. Battery Gauge Indicator
5. On Time Treatment	12. Removable Card IN with Residual Capacity
6. Heart Rate (BPM)	13. Microphone ON / OFF
7. Impedance (ohms)	14. Current Date and Time

3.5 AED DESCRIPTION

Saver One D is an easy-to-use **Automated External Defibrillator (AED)** designed to administer safe treatments against SCA and able to give visual details and rescue information throughout a very large colour display (5.7").

Handy and fast, is the right choice for harsh, outdoor or mobile use for more expertise rescuers or paramedics to act anywhere. Practical and intuitive, with CPR guidance and clear instructions able to support users through rescue protocol for effective actions.

Able to detect and automatically analyse the victim's heart rate and capable of delivering one or more defibrillation shocks if a ventricular fibrillation (VF) or ventricular tachycardia (VT monomorphic or polymorphic with heartbeat >180) is detected. The energy is supplied by exponential truncated biphasic (B.T.E.) electric shock able to self-adapting to the patient's thoracic impedance.

Saver One D has **ECG Monitoring** capability and could print (optional) ECG saved data on an external thermal printer through its Irda Port.

Saver One D is available with two energy level versions:

- **Standard** **Maximum output at 200J** Saver One D (SVO-B0004)
- **Power** **Maximum output at 360J** Saver One D (SVO-B0005)

Saver One D can be used with Non-Rechargeable Battery Li-SOCl₂ (SAV-C0903) or Rechargeable Battery Li-Ion (SAV-C0011) and with Adult Defibrillation Pads (SAV-C0847) or Paediatric Pads (SAV-C0016).

3.6 SERVICE MINI-DISPLAY

The LCD Mini-Display is helpful for receiving information on the status of AED and/or for Service.

In STANDBY Mode will confirm that the AED is ready for use by displaying a "Check Mark" and the Battery Gauge Indicator informing on the residual charge of the battery.

In STANDBY and OPERATING Mode will run text with "Error Code" (warnings for service required) in faulty AED conditions.

3.7 MENU & SET-UP

Any AED has a factory standard configuration. Some features can be modified by the user navigating into the MENU and approaching parts of the AED software.

At the first start-up, after the activation test, it's recommended to set-up the AED at user's pleasure and vary the date and time.

AED can be set, in Operating Mode, using the following buttons and procedure:

ENTRY MENU BUTTON	UP BUTTON	DOWN BUTTON
		
Entering the MENU Entering the SECTION of the menu Confirming the SELECTION	Scrolling UP	Scrolling DOWN

The MENU has different sections on pages.

- Press the Entry Menu Button to enter its first page.

Once entered, the first page will display the following Sections:

1. **SEMIAUTOMATIC**
2. **ECG MONITORING**
3. **SETTINGS**
4. **SYSTEM INFORMATION**
5. **PRINT** (will disappear if the AED is operating a rescue)
6. **Exit**

Settings

- Enter the MENU
- Scroll down till “**SETTINGS**” and press the Entry Menu Button.

In this section is possible to set-up the following:

- a) To vary the **VOLUME** from 10 to 100%
- b) To choose **MICROPHONEOFF** if rescue voice and environmental recordings is not required
- c) To vary the display **CONTRAST** from 0 to 100%
- d) To change current **LOCAL TIME**
- e) To change the **LANGUAGE** (if AED equipped with more than one)
- f) To choose the **CPR RATIO** 15:2 if Paediatric Pads are installed and users are ALS personnel

Note: “CPR Ratio” option will appear whenever paediatric pads are connected to AED.

In case of PALS (Paediatric ALS) rescue attended by two or more healthcare professionals with a duty to respond, this option should be activated as required by Guidelines in force, and the CPR should have the new ratio of 15:2 (15 compressions and 2 rescue breaths).

The display will show the new Protocol and CPR Ratio: **PEDIATRIC 15:2**

Once the AED is turned off, this option will return in its default operation with the ratio 30:2.

- Scroll down till “**EXIT**” to confirm the new set-up.

The configuration chosen will be kept in memory for the next AED start-up and new changes.

System Information

- Enter the MENU
- Scroll down till “**SYSTEM INFORMATION**” and press the Entry Menu Button.

Once entered, this section will display:

1. **MODEL TYPE** (will inform about the AED Model in use)
2. **SERIAL NUMBER** (will inform about the AED Serial Number)
3. **SOFTWARE VERSION** (will inform about the Software Version in use)
4. **POWER SUPPLY**
5. **Exit**

- To have information about the Battery in use, scroll down till “**POWER SUPPLY**” and press the Entry Menu Button.

Once entered, this section will display the following information:

- a) The **TYPE OF BATTERY** connected (disposable or rechargeable)
- b) The **REMAINING CAPACITY** (percentage) of the battery
- c) The **CHARGING COUNTS**(available only with rechargeable battery installed)
- d) The **VOLTAGE**

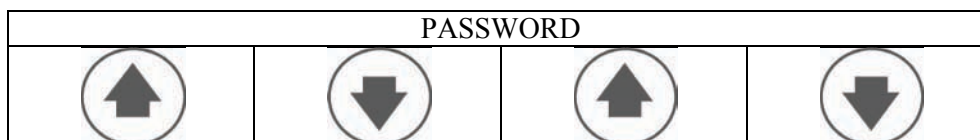
- Scroll down until “**EXIT**” to go out from this section.

3.8 ECG MONITORING

Saver One D is able to work in **ECG Monitoring** (protected mode) allowing for watch over the rhythm and heart rate while using Defibrillation Pads or standard ECG Electrodes.

This modality is only intended for specialized medical personnel and is password protected.

- Enter the MENU
- Scroll down until “**ECG MONITORING**” and press the Entry Menu Button
- Then press this sequence **UP, DOWN, UP, DOWN** as password required



The device is able to collect 1 ECG waveform Lead II with 2 different accessories:

1. Multifunction Defibrillation Pads
2. Standard ECG Electrodes attached to a separated 2-Lead Patient Monitoring reusable Cable



WHILE OPERATING THIS MODALITY, THE DEVICE CANNOT GIVE ANY SHOCK.
IT WILL KEEP JUST ANALYSING HEARTH RYTHM.
IF A SHOCK IS NEEDED OR WANT TO GO OUT FROM THIS MODALITY, PRESS
TWICE THE ENTRY MENU BUTTON IN ORDER TO SWITCH THE AED IN SEMI-
AUTOMATIC MODE.

Note: The AED doesn't allow printing ECG in real time (while using this modality).

ECG Electrodes and Reusable Monitoring Cable

The Patient Monitoring reusable Cable (SAV-C0017), rated Type CF, is equipped with two spring-clip terminals for connecting standard pre-gelled disposable ECG Electrodes (option).

The quality of ECG data displayed on the device is the direct consequence of the electrical signal quality received by the electrodes.

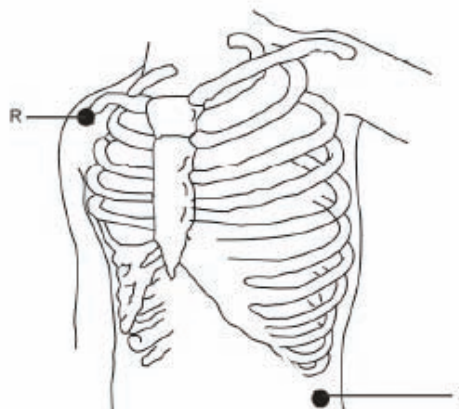
- Connect the Monitoring Cable to AED and clip the two ECG Electrodes.
- Place the two ECG Electrodes to the patient as follows:

Red (“R” code IEC) ECG Electrode

To be placed close to the right shoulder directly below the clavicle.

Green (“F” code IEC) ECG Electrode

To be placed on the left side of the hypogastrium



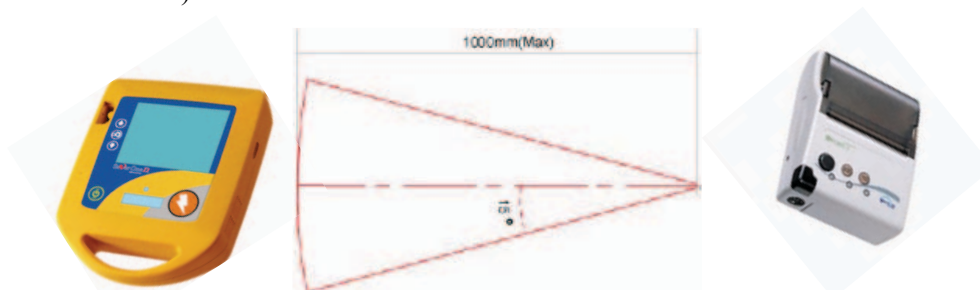
AED will start monitoring the hearth rhythm.

3.9 PRINTING (option)

This section is available only for **Saver One D** purchased with the **Print-Ready Configuration** (Conf-Print).

The Conf-Print provides an AED equipped with IrDA Port (Infrared systems) able to communicate with the external Thermal Printer PORTI-S30 (SAV-C0018) and print ECG saved in the AED.

Once turned on, establish the connection between both devices by approaching the Thermal Printer's infrared (maximum distance 10cm.) to the AED's IrDA Port.



- Enter the MENU

If the connection is established the text prompt “**READY**” will be displayed. Otherwise there will be “**NO CONNECTION**”.

- Select the file from the **ARCHIVE** scrolling down between the files saved into AED.

The Archive contains various files (AEDFILE) related to multiple sessions saved and divided by:

1. The name (nnnnnnXX.aed - where the first 6 digits represents the date of rescue)
2. A progressive number of the file on the total of saved files (2/30 – the second file on 30 as total saved)
3. The date and time of the rescue
4. The volume (expressed in Kb) of the file

- Scroll down till “**PRINT**” (is not shown during a rescue) and press the Entry Menu Button for printing.
- Scroll down until “**EXIT**” to go out from this section.



SEMI-AUTOMATIC AED
With ECG MONITORING
And MANUAL Override

4.1 QUICK START GUIDE

This is a quick start guide included into the carry case of AED.



4.2 STANDARD BOX CONTENTS

The **Standard Basic Configuration** (Conf-Norm) includes:

- 1 AED unit
- 1 Pair of Adult defibrillation pads
- 1 Non-Rechargeable Battery
- 1 Carrying Case (with a Quick Start Guide)
- 1 Quick Operating Guide and a User Manual

Available optional Configurations:

1. **Rechargeable Configuration** (Conf-Rech)
(AED unit, Pair of Adult defibrillation pads, Rechargeable Battery, Charger Station, Carrying Case)
2. **Print Ready Configuration** (Conf-Print)
(AED unit equipped with IrDA Port, Thermal Printer PORTI-S30, Pair of Adult defibrillation pads, Non-Rechargeable Battery, Carrying Case)
3. **Rechargeable & Print Ready Configuration**(Conf-Rech/Print)
(AED unit equipped with IrDA Port, Thermal Printer PORTI-S30, Pair of Adult defibrillation pads, Rechargeable Battery, Charger Station, Carrying Case)

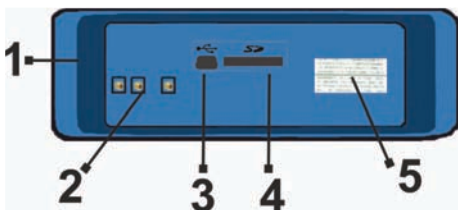
4.3 AED PARTS

The following drawings show the AED parts and their locations.



1. Battery	7. Status LED Indicator
2. IrDA Port (option)	8. ON/OFF switch
3. Disarm / Energy / Charging buttons	9. Microphone
4. Speaker	10. Pads or ECG cable connection port
5. Shock button	11. MENU buttons
6. Service LCD Mini-Display	12. TFT Colour screen 5.7"

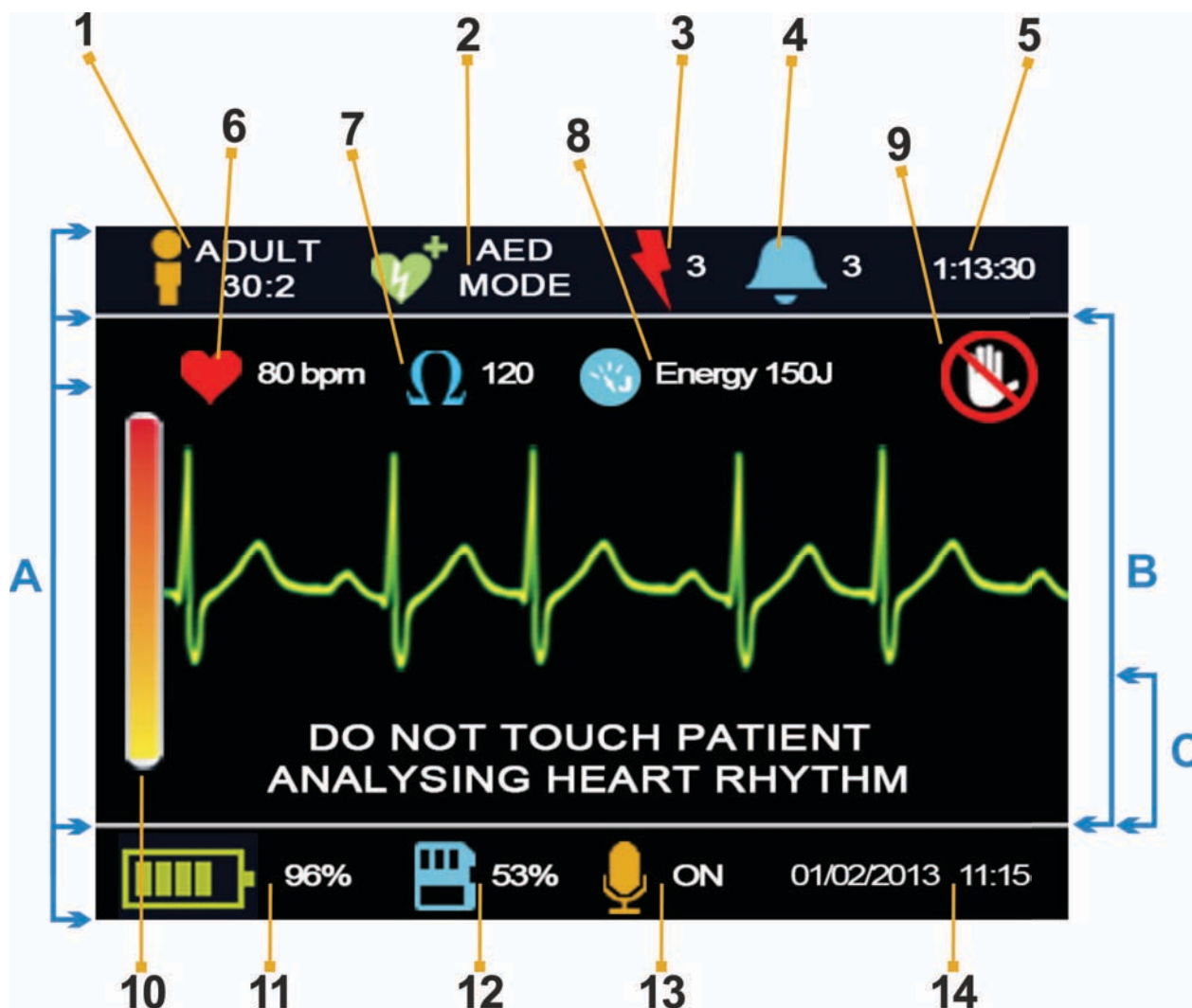
Rear View



1. Battery compartment
2. Contact PINS
3. USB Port
4. Removable SD Card seat
5. Warranty seal

4.4 TFT COLOUR DISPLAY 5.7"

The following drawings show the display equipped on *Saver One P*.



(This example is given for a device equipped with English software.
Your AED should be equipped with the prompts in your language)

A. Rescue and AED Set-Up Information Field
B. Graphic Area active during rescue.
C. Text Area running during rescue

1. Protocol (AD/PED) and CPR Ratio in use	8. Energy Level to Deliver
2. Modality (AED/ECG/SYNC/ASYN) in use	9. Icon Don't Touch Patient
3. Shock Counts	10. Charging Bar (progressing)
4. Fibrillation Alarm Counts	11. Battery Gauge Indicator
5. On Time Treatment	12. Removable Card IN with Residual Capacity
6. Heart Rate (BPM)	13. Microphone ON / OFF
7. Impedance (ohms)	14. Current Date and Time

4.5 AED DESCRIPTION

Saver One P is a tough, small and lightweight **dual-mode defibrillator** easy to carry and use anywhere. The right choice for harsh, outdoor or mobile use, able to administer safe treatments against SCA and give visual details and rescue information throughout a very large colour display (5.7”).

Highly flexible and versatile with advanced capabilities for any scenery: a **Semi-Automatic AED** (per default) reliable for BLS rescuers which can be simply switched to a **MANUAL** defibrillator giving to ALS responders the best decision-making control for a manual shock timing with **Unsynchronized** or **Synchronized Cardioversions**.

Saver One P has **ECG Monitoring** capability and could print (optional) ECG saved data on an external thermal printer throughout its Irda Port.

Saver One P is available with two energy level versions:

- **Standard** **Maximum output at 200J** Saver One P (SVP-B0006)
- **Power** **Maximum output at 360J** Saver One P (SVP-B0007)

Saver One P can be used with Non-Rechargeable Battery Li-SOCl₂ (SAV-C0903) or Rechargeable Battery Li-Ion (SAV-C0011) and with Adult Defibrillation Pads (SAV-C0847) or Paediatric Pads (SAV-C0016).

4.6 SERVICE MINI-DISPLAY

The LCD Mini-Display is helpful for receiving information on the status of AED and/or for Service.

In STANDBY Mode will confirm that the AED is ready for use by displaying a “Check Mark” and the Battery Gauge Indicator informing on the residual charge of the battery.

In STANDBY or OPERATING Mode will run text with “Error Code” (warnings for service required) in faulty AED conditions.

4.7 MENU & SET-UP

Any AED has a factory standard configuration. Some features can be modified by the user navigating into the MENU and approaching parts of the AED software.

At the first start-up, after the activation test, it’s recommended to set-up the AED at user’s pleasure and vary the date and time.

AED can be set, in Operating Mode, using the following buttons and procedure:

ENTRY MENU BUTTON	UP BUTTON	DOWN BUTTON
		
Entering the MENU Entering the SECTION of the menu Confirming the SELECTION	Scrolling UP	Scrolling DOWN

The MENU has different sections.

- Press the Entry Menu Button to enter the first page.

Once entered, the first page will display the following Sections:

1. **SEMIAUTOMATIC**
2. **MANUAL SYNCHRONOUS**
3. **MANUAL ASYNCHRONOUS**
4. **ECG MONITORING**
5. **SETTINGS**
6. **SYSTEM INFORMATION**
7. **PRINT** (will disappear if the AED is operating a rescue)
8. **Exit**

Settings

- Enter the MENU
- Scroll down till “**SETTINGS**” and press the Entry Menu Button.

In this section it is possible to set-up the following:

- a) To vary the **VOLUME** from 10 to 100%
- b) To choose **MICROPHONE OFF** if don't require voice and environmental recordings
- c) To vary the display **CONTRAST** from 0 to 100%
- d) To change current **LOCAL TIME**
- e) To change the **LANGUAGE** (if AED equipped with more than one)
- f) To choose the **CPR RATIO** 15:2 if Paediatric Pads are installed and users are ALS personnel
- g) To choose **CPR HELP** OFF if don't require CPR guidance during the rescue session when using the AED in Semi-Automatic mode

Note: “CPR Ratio” option will appear whenever paediatric pads are connected to AED.

In case of PALS (Paediatric ALS) rescue attended by two or more healthcare professionals with a duty to respond, this option should be activated as required by Guidelines in force, and the CPR should have the new ratio of 15:2 (15 compressions and 2 rescue breaths).

The display will show the new Protocol and CPR Ratio: **PEDIATRIC 15:2**

Once the AED is turned off, this option will return in its default operation with the ratio 30:2.

Note: “CPR Help” (ON/OFF option) is used by the rescuer if guidance (voice prompts and metronome) during the CPR sequence is needed or not, when using the AED in Semi-Automatic Mode.

If optioned OFF, the AED will run only text prompt on the colour display but will perform 2 minutes of silence during the CPR (not voice messages neither metronome).

Once the AED is turned off, this option will return in its default operation ON.

- Scroll down till “**EXIT**” to confirm the new set-up.

The configuration chosen will be kept in memory for the next AED start-up and new changes.

System Information

- Enter the MENU
- Scroll down till “**SYSTEM INFORMATION**” and press the Entry Menu Button.

Once entered, this section will display:

1. **MODEL TYPE** (will inform about the AED Model in use)
2. **SERIAL NUMBER** (will inform about the AED Serial Number)
3. **SOFTWARE VERSION** (will inform about the Software Version in use)
4. **POWER SUPPLY**
5. **Exit**

- To have information about the Battery in use, scroll down till “**POWER SUPPLY**” and press the Entry Menu Button.

Once entered, this section will display the following information:

- The **TYPE OF BATTERY** connected (disposable or rechargeable)
- The **REMAINING CAPACITY** (percentage) of the battery
- The **CHARGING COUNTS**(available only with rechargeable battery installed)
- The **VOLTAGE**

➤ Scroll down until “**EXIT**” to go out from this section.

4.8 MANUAL MODE & SYNCHRONIZED CARDIOVERSION

Saver One P is capable to operate in MANUAL MODE by simply selecting the modality required:

- MANUAL SYNCHRONOUS
- MANUAL ASYNCHRONOUS



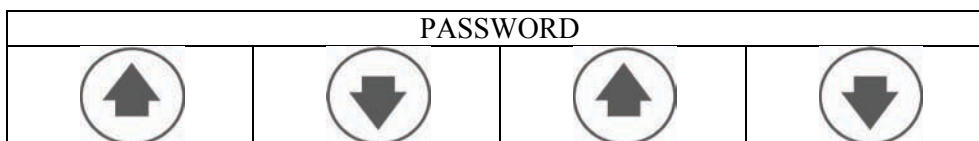
BOTH MODALITIES HAS TO BE USED ONLY BY ALS PERSONNEL.

IF YOU ARE NOT SURE ON WHAT TO DO IS PREFERABLE TO LEAVE AED IN ITS DEFAULT SEMI-AUTOMATIC MODALITY AND USE IT WITH THE STANDARD DEFAULT RESCUE PROTOCOL.

Once turned on, the AED is always running in Semi-Automatic Mode (default modality).

Manual Modalities are protected sections where an entry password is required.

- Enter the MENU
- Scroll down and choose the “**MANUAL**” modality required, then press the Entry Menu Button
- Press this sequence **UP, DOWN, UP, DOWN** as password required



The display will show the new Modality in use:

- **SYNC MODE** for the Manual Synchronous
- **ASync MODE** for the Manual Asynchronous

For operating with both Manual Modalities, the rescuer should use the following buttons:

ENERGY	CHARGING	DISARM
Selecting the energy to deliver (shock)	Arming AED (charging for shock)	Disarming AED

- Press the “**ENERGY**” button to enter the section of the energy levels available in the device:

STANDARD Version Max 200J	50J	100J	150J	200J	250J	300J	360J
POWER Version Max 360J							

- Scroll UP / DOWN for selecting the desired energy, then press the Entry Menu Button to confirm
- Press the “**CHARGING**” button to arm the AED and get it ready for shock

The AED will prompt “*Do not touch patient. Charging for the shock*” and a charging bar is progressing on the colour display.

Once armed and ready to deliver a defibrillation shock, the prompt “*Press shock button*” will be heard and the shock button starts flashing.

- Press the “**SHOCK**” button (being sure no one is touching the patient) to deliver a shock

If the shock button is not pressed within 18 seconds of hearing the prompt, the AED will disarm with the voice prompt “*Shock cancelled. Shock button not pressed*”.

The AED could be disarmed at any time by pressing the “**DISARM**” button and the prompt “*Shock cancelled*” is heard.

After the AED delivers the defibrillation shock, the voice prompt will say “*Shock Delivered*” and the AED will keep analysing the patient while waiting for the next rescuer’s command.

When using both Manual Modalities, the CPR guidance is automatically OFF. There will be no voice messages or metronome during CPR. On the screen will be displayed only text prompts and pictograms.

MANUAL SYNCHRONOUS

The Manual Synchronous Mode will able the rescuer to provide Synchronized Cardioversions.

The Synchronized Cardioversion is a shock delivery that is timed with the QRS complex.

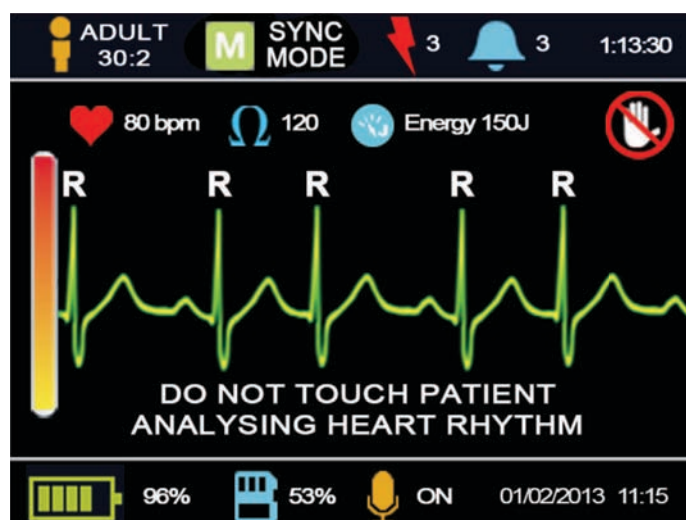
The most common use of Cardioversion is to treat atrial fibrillation or atrial flutter. But Cardioversion may also be used to treat unstable supraventricular tachycardia, which could lead to ventricular fibrillation.

This synchronization avoids shock delivery during the relative refractory portion of the cardiac cycle (when a shock could produce ventricular fibrillation).

Cardioversion may be a necessary procedure when drugs alone have not been able to convert an arrhythmia to a normal heart rhythm. Cardioversion restores the normal heart rate and rhythm, allowing the heart to pump more effectively.

By pressing the MANUAL SYNCHRONOUS mode, once entered the MENU, the AED will start operating with its SYNC MODE and the AED synchronizing circuit will detect the patient's R-wave.

The SYNC MODE and R-waves are displayed.



Once selected the energy to deliver and charged the AED for the shock, after the voice prompts “*Press shock button*“, the rescuer has to press and held the shock button until the AED will discharge with the next detected R-wave.

When the shock button is pressed there will be a delay in the shock.

Delay time between QRS peak and effective shock is maximum 50ms.

During this delay, the AED reads and synchronizes with the patients ECG rhythm. This occurs so that the shock can be delivered with the peak of the R-wave in the patients QRS complex, thus avoiding the vulnerable T wave segment of the cardiac cycle.

MANUAL ASYNCHRONOUS

By using the Manual Asynchronous Mode, the rescuer can provide Unsynchronized Cardioversions. A standard defibrillation shock which is delivered as soon as the shock button is pressed.

Unsynchronized Cardioversion is used when there is no coordinated intrinsic electrical activity in the heart (pulseless VT/VF) and the shock may fall randomly anywhere within the cardiac cycle (QRS complex).

By pressing the MANUAL ASYNCHRONOUS mode, once entered the MENU and provided the password, the AED will start operating with its ASYNC MODE.

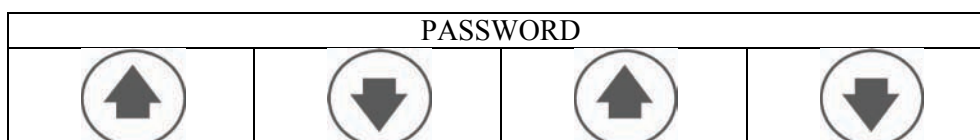
Select the desired energy level to deliver, then charge the AED by pressing the Charging button and, finally press the shock button as soon as the voice prompt “*Press shock button*“ is heard.

4.9 ECG MONITORING

Saver One D is able to work in **ECG Monitoring** (protected mode) allowing for watch over the rhythm and heart rate while using Defibrillation Pads or standard ECG Electrodes.

This modality is only intended for specialized medical personnel and is password protected.

- Enter the MENU
- Scroll down until “**ECG MONITORING**” and press the Entry Menu Button
- Then press this sequence **UP, DOWN, UP, DOWN** as password required



The device is able to collect 1 ECG waveform Lead II with 2 different accessories:

3. Multifunction Defibrillation Pads
4. Standard ECG Electrodes attached to a separated 2-Lead Patient Monitoring reusable Cable



WHILE OPERATING THIS MODALITY, THE DEVICE CANNOT GIVE ANY SHOCK.
IT WILL KEEP JUST ANALYSING HEARTH RYTHM.
IF A SHOCK IS NEEDED OR WANT TO GO OUT FROM THIS MODALITY, PRESS
TWICE THE ENTRY MENU BUTTON IN ORDER TO SWITCH THE AED IN SEMI-
AUTOMATIC MODE.

Note: The AED doesn't allow printing ECG in real time (while using this modality).

ECG Electrodes and Reusable Monitoring Cable

The Patient Monitoring reusable Cable (SAV-C0017), rated Type CF, is equipped with two spring-clip terminals for connecting standard pre-gelled disposable ECG Electrodes (option).

The quality of ECG data displayed on the device is the direct consequence of the electrical signal quality received by the electrodes.

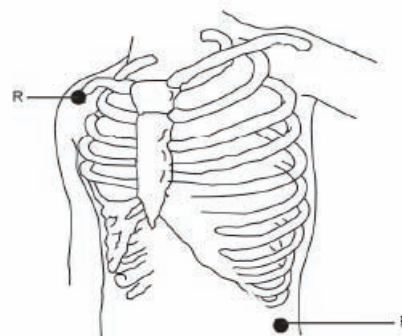
- Connect the Monitoring Cable to AED and clip the two ECG Electrodes.
- Place the two ECG Electrodes to the patient as follows:

Red (“R” code IEC) ECG Electrode

To be placed close to the right shoulder directly below the clavicle.

Green (“F” code IEC) ECG Electrode

To be placed on the left side of the hypogastrium



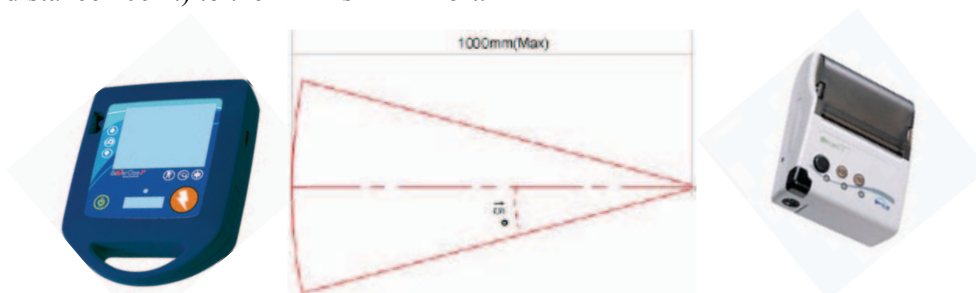
AED will start monitoring the hearth rhythm.

4.10 PRINTING (option)

This section is available only for **Saver One P** purchased with the **Print-Ready Configuration** (Conf-Print).

The Conf-Print provides an AED equipped with IrDA Port (Infrared systems) able to communicate with the external Thermal Printer PORTI-S30 (SAV-C0018) and print ECG saved in the AED.

Once turned on, establish the connection between both devices by approaching the Thermal Printer’s infrared (maximum distance 10cm.) to the AED’s IrDA Port.



- Enter the MENU of the AED

If the connection is established the text prompt “**READY**” will be displayed. Otherwise there will be “**NO CONNECTION**”.

- Select the file from the **ARCHIVE** scrolling down between the files saved into AED.

The Archive contains various files (AEDFILE) related to multiple sessions saved and divided by:

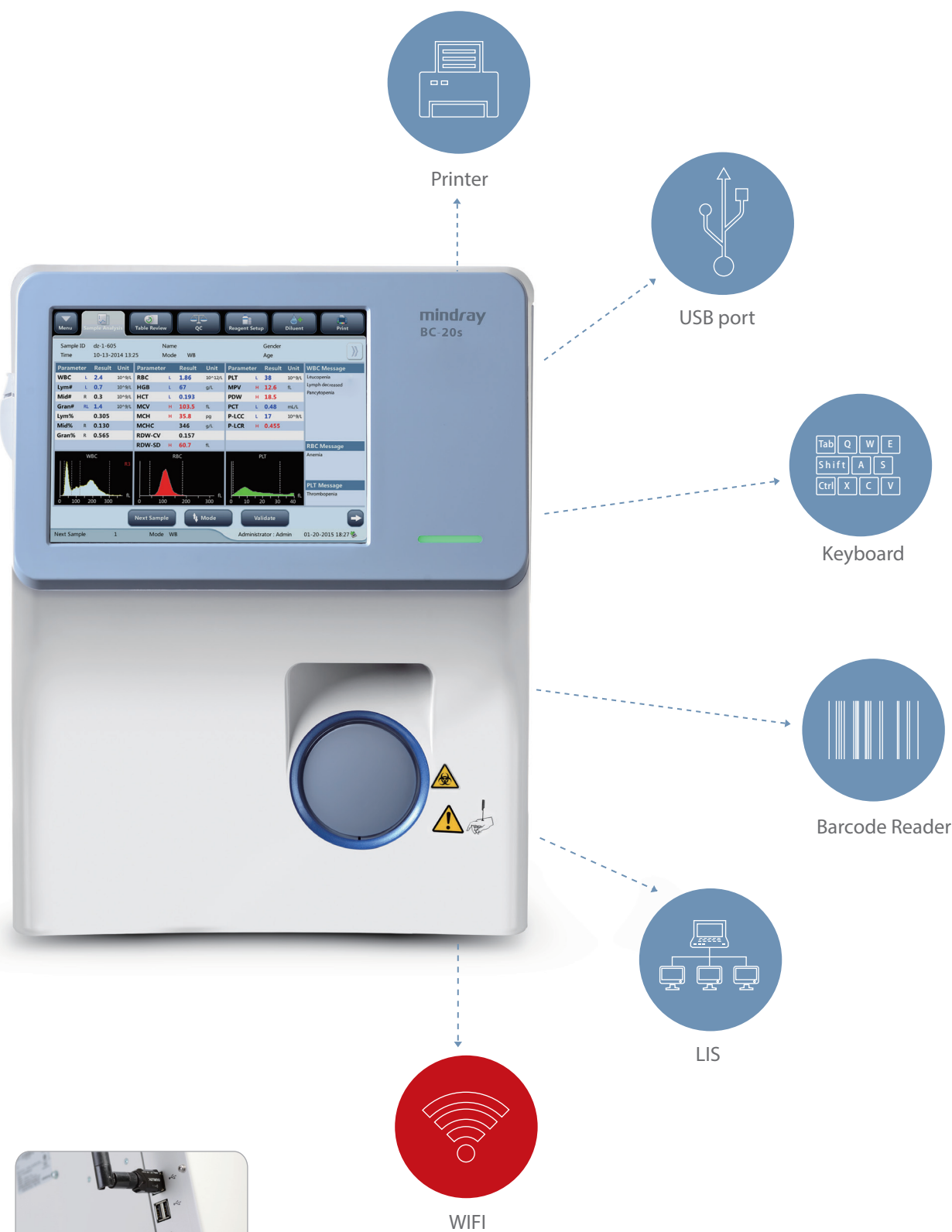
1. The name (nnnnnnXX.aed - where the first 6 digits represents the date of rescue)
2. A progressive number of the file on the total of saved files (2/30 – the second file on 30 as total saved)
3. The date and time of the rescue
4. The volume (expressed in Kb) of the file

- Scroll down till “**PRINT**” (is not shown during a rescue) and press the Entry Menu Button for printing.
- Scroll down until “**EXIT**” to go out from this section.

Saver One®



eVeryday
eVerybody
eVerywhere



WIFI capability provides you an added option for data communication together with bi-directional LIS, USB port and LAN port, barcode reader, printer and keyboard.

BC-20s

Auto Hematology Analyzer

Technical Specifications

Principles

Impedance method for WBC, RBC and PLT counting
Cyanide free reagent for hemoglobin test

Performance

Parameter	Linearity Range	Precision (CV %)	Carryover
WBC($10^9/L$)	0-100	$\leq 3.5\%$ (4.0-6.9) $\leq 2.0\%$ (7.0-15.0)	$\leq 0.5\%$
RBC($10^{12}/L$)	0-8.00	$\leq 1.5\%$ (3.5-6.5) $\leq 1.0\%$ (70-110)	$\leq 0.5\%$
HGB(g/L)	0-280	$\leq 1.5\%$ (100-180) $\leq 1.0\%$ (100-149)	$\leq 0.5\%$
MCV(fL)		$\leq 1.0\%$ (150-500)	
PLT($10^9/L$)	0-1000	$\leq 5.0\%$ (100-149) $\leq 4.0\%$ (150-500)	$\leq 1.0\%$

Parameters

19 parameters: WBC, Lymph#, Mid#, Gran#, Lymph%, Mid%, Gran%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT
3 histograms for WBC, RBC and PLT

Reagent

M-30D DILUENT
M-30CFL LYSE
PROBE CLEANSER

Sample Volume

Prediluted mode 20 μ L
Whole blood mode 9 μ L

Throughput

40 samples per hour

Display

8.4 inch TFT Touch Screen

Data Storage Capacity

Up to 200,000 results including numeric and graphical information

Communication

LAN Port supports HL7 protocol
Support bi-directional LIS

Interface

4 USB port (for external printer, software upgrade, barcode reader, WIFI adapter, keyboard and mouse), LAN port (1)

Printout

Thermal recorder, 50 mm wide paper, various printouts formats
External printer optional

Operating Environment

Temperature: 10°C~40°C
Humidity: 10%~90%
Air pressure: 70kPa~106kPa

Power Requirement

100V-240V
 $\leq 300VA$
50Hz/60Hz

Dimension and Weight

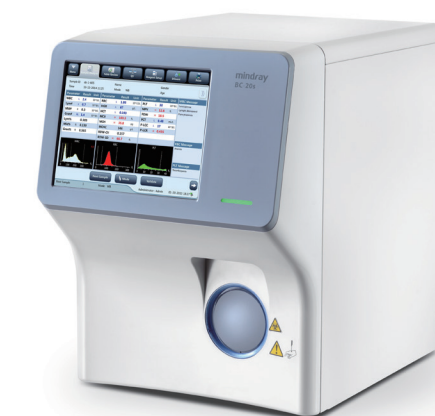
Dimension: Depth(410 mm) x width(300 mm) x height(400 mm)
Weight: $\leq 20Kg$



BC-20s

Auto Hematology Analyzer

Minimum Size,
Maximum Capability



Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan, Shenzhen 518057, P.R. China
Tel: +86 755 8188 8998 Fax: +86 755 26582680
E-mail: intl-market@mindray.com www.mindray.com
Mindray is listed on the NYSE under the symbol "MR"

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P/N: ENG-BC-20s-210285x6-20150331

mindray

mindray
healthcare within reach



What a 3-part should be

At Mindray we pride ourselves in our dedication and experience in developing better solutions for small labs. Our new line of 3-part hematology analyzers is the culmination of that effort. Compact yet powerful, full featured yet affordable, the BC-20s is what a 3-part analyzer should be.



Exclusive Feature

Detailed flag information never before seen on a 3-part analyzer. Provides information useful for diagnosis including WBC flag, RBC flag and PLT flag.

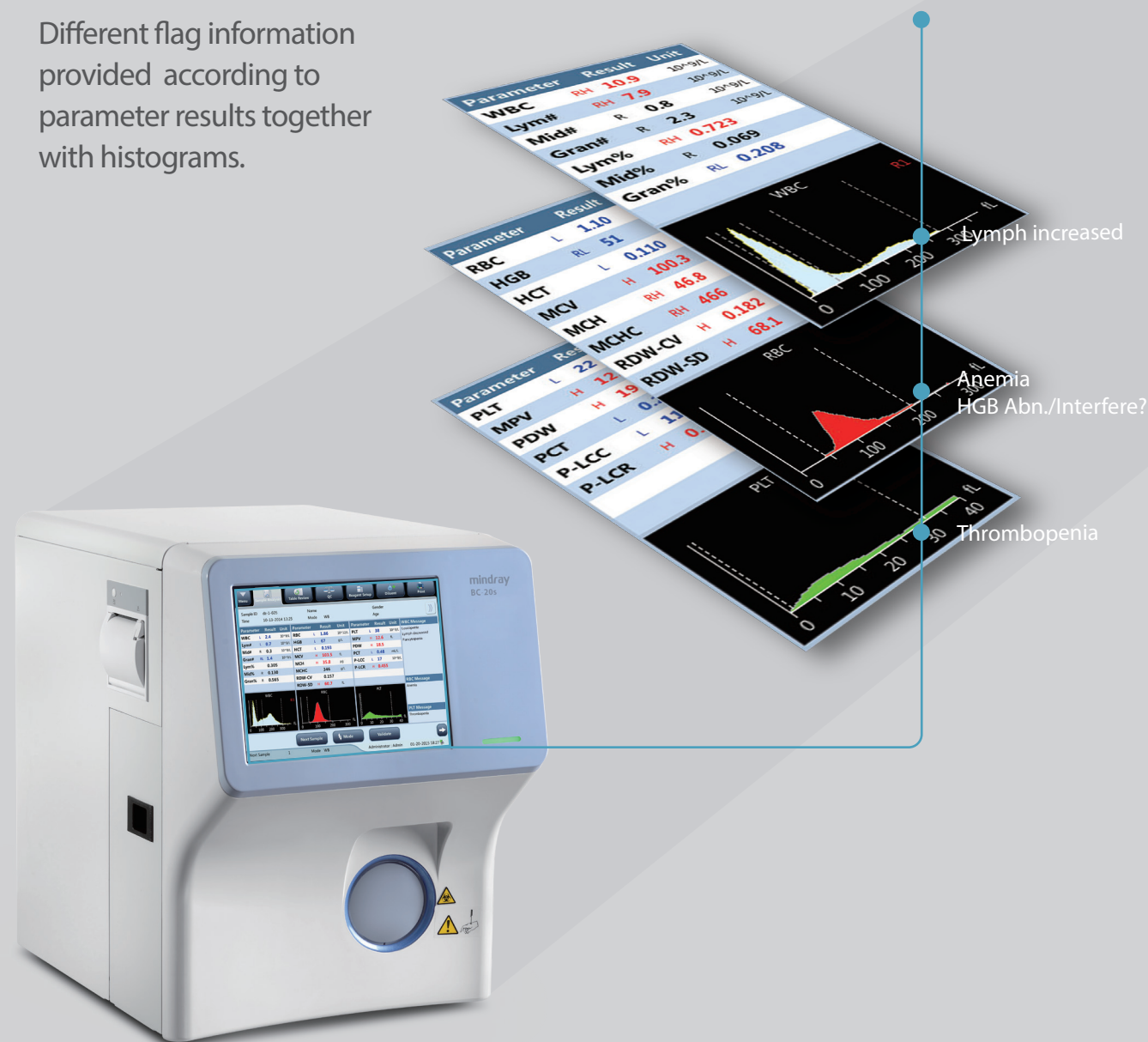
BC-20s Auto Hematology Analyzer

Sample 1 : BC-20s shows flag “Lymph increased” which means a high number of Lymphocytes and/or immature cells. Meanwhile R1 flag is also displayed. Two kinds of flag messages are both supported to ensure clinicians have better understanding of sample results.

Sample 2 : Flag “Anemia” and “HGB Abn./Interfere?” are displayed. They mean the sample has shows either signs of Anemia, Abnormal Hemoglobin or sample is interfered such as by high value of Leukocytes or Agglutinated Erythrocytes.

Sample 3 : Flag “Thrombopenia” indicator is shown together with Platelets low flag.

Different flag information provided according to parameter results together with histograms.



Better Usability

Minimum size with the footprint similar to that of a 17 inch laptop, with space saving design that allows internal storage of lyse giving small labs more space. 8.4 inch TFT touch screen together with our powerful software enhances user operations and experience.

Higher Efficiency

New technology that eliminates the need for cleanser and rinse, reducing the number of reagents needed while at the same time lowering overall reagent consumption. Flexible packaging of reagents, with normal and small sizes to better cater to the needs of different daily sample volumes.



Enhanced Performance

Higher throughput at 40 tests per hour.

Micro sample volume at 9.0uL for whole blood mode with capillary whole blood samples supported, perfect for pediatric samples.

BC-5150

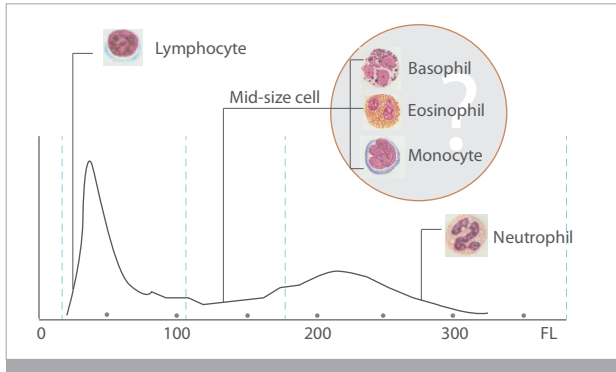
Auto Hematology Analyzer

A "CUTE" 5-part



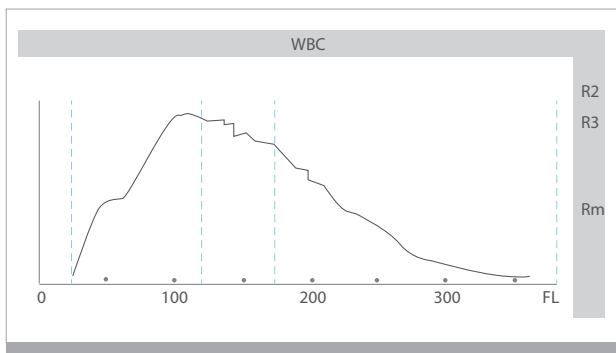
Why do we need 5-part hematology analyzers?

WBC differential: 3-part



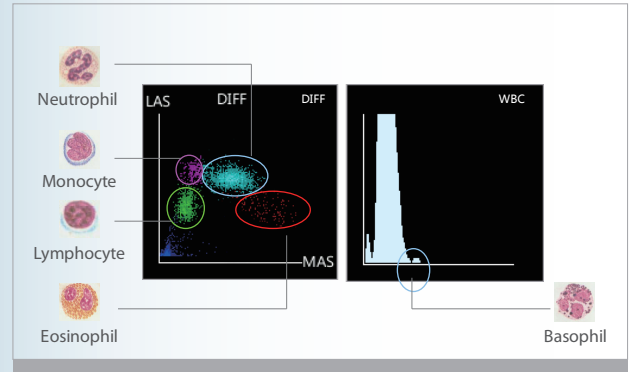
3-part hematology analyzers can not differentiate Basophil, Eosinophil and Monocyte. Additionally, Lymphocyte and Neutrophil results are easily affected by abnormal cells.

Flag information: 3-part



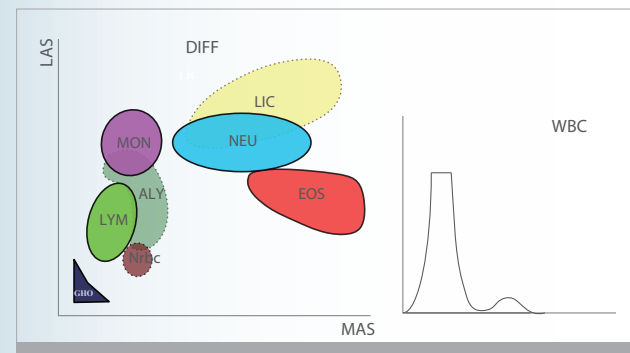
WBC histogram only indicates regional abnormal graph, it can't bring specific flags for different clinical cases.

WBC differential: 5-part



5-part hematology analyzers can provide Lymphocyte, Monocyte, Neutrophil, Eosinophil and Basophil results for every sample. Additionally, the 5-part results are less affected by abnormal cells.

Flag information: 5-part



5-part hematology analyzers provide more detailed and specific flag information. Users are able to clearly understand the clinical significance of flags and make a decision.



Dr Marisela Ramos, lab manager

Users are able to access our tailored innovation and intelligent diagnosis support to safeguard their diagnoses decisions with maximum confidence.

She said: "we upgraded to a 5-part hematology analyzer 3 months ago, and it's been working very well. Our lab has lots of abnormal samples, such as Eosinophilia and Monocytosis samples. We could only get the information that the mid-size cells percentage was higher than normal level, but couldn't distinguish which kind of cells increased exactly. Now, the 5-part hematology analyzer provides flags directly, which reduces smears need to be reviewed, and significantly improves our work efficiency."

BC-5150

Auto Hematology Analyzer

Based on Mindray's continuous innovation in hematology field, BC-5150 is especially tailored to assist diagnostic labs who need full CBC + 5-part results, with relatively low daily sample volume, restricted lab space and tight budget.

As the lightest and most compact 5-part hematology analyzer so far from Mindray, BC-5150 is a highly user-friendly and innovative analyzer that offers cost efficient CBC and 5-part white cell differential results. It is targeted to fulfill and exceed the demands of our global customers by providing more accurate, more efficient and more innovative solutions for labs.

WBC 5-part differentiation, 25 reportable parameters and 24 research parameters, 3 histograms and 4 scattergrams

Whole blood mode, Capillary whole blood mode and Prediluted mode

Tri-angle Laser scatter + Chemical dye + Flow cytometry technology

Dedicated optical counting channel for Basophil measurement

Powerful capability of flagging abnormal cells

10.4 inch large TFT touch screen with user-friendly software

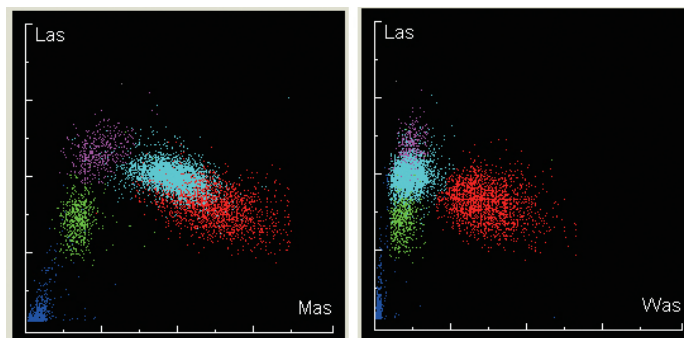
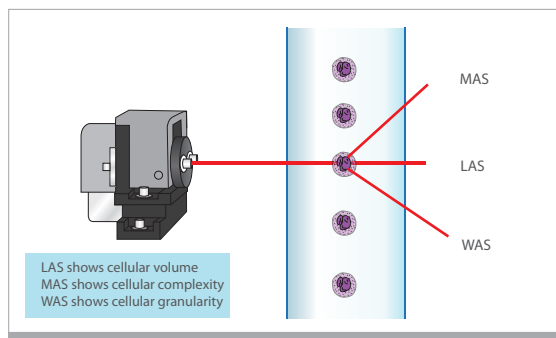
Large storage capacity: up to 250,000 samples

Throughput: 60 samples per hour

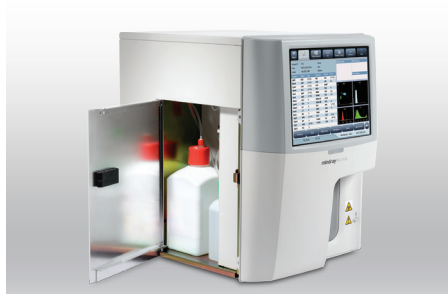
Sample volume is only 15 μ L which is ideal for pediatrics



Tri-angle laser scatter + focused flow + chemical dye, creating the possibility for a better 5-part WBC differentiation even on samples with high Eosinophil.



BC-5150, the 5-part hematology analyzer offers a great solution for clinical labs, especially for those who have limited space. Its compact foot-print is a result of innovative technology improvements, including miniaturized semi-conductor laser source, highly integrated electronic boards and optimized liquid handling system.



Compact

Two kinds of lyse reagents are located inside of BC-5150, which helps the small labs to save space.



Utility

The 10.4 inch TFT touch screen with a wide viewing angle, brings convenience to clinicians. Users can complete all instrument operations on the screen, practically eliminating the need for an external PC.



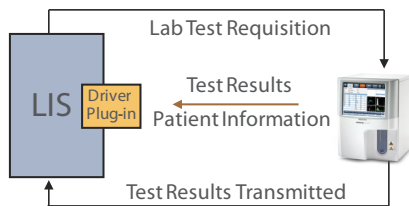
BC-5150 inherits its convenient and proven powerful software design from BC-6800 and BC-3600 platforms, the friendly interface is ideal for small sized labs.



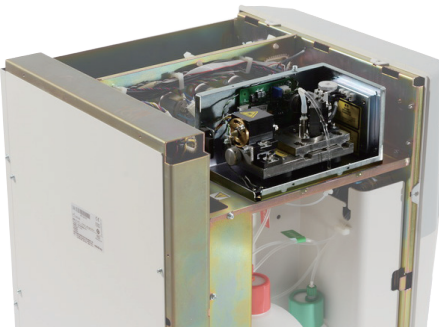
Running capillary blood through the sample probe directly is more convenient for the users in children's hospitals, etc. For Prediluted mode, BC-5150 has higher dilution ratio than other 5-part hematology analyzers, thus it brings a better mixing effect.



4 USB ports are located on the instrument's left side. They permit BC-5150 users to transmit data conveniently and connect with printers, keyboard, mouse, barcode scanner, etc.

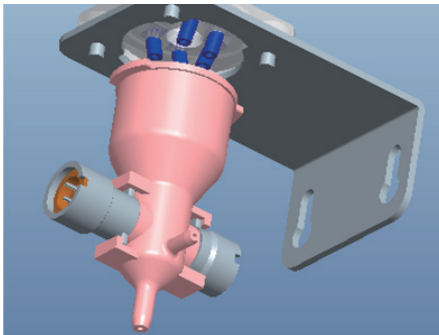


BC-5150 supports bi-directional LIS with test results and patient information. HL7 protocol is supported as well.



Technology

Compared with traditional helium neon laser or argon laser, semi-conductor laser has smaller size, lower cost and longer life cycle.



Improved DC impedance technology is used to count and size the RBC and PLT. The smaller counting aperture (50 μm in diameter) provides better performance on samples with low PLT.



Efficient

Only three routine reagents are required. These have 2 years shelf life and also less consumed by BC-5150. Original QC and calibrator are also provided to ensure the hematology analyzer's traceability and testing quality.

Technical Specifications

Principles

Impedance method for RBC and PLT counting

Cyanide free reagent for hemoglobin test

Flow Cytometry (FCM) + Tri-angle laser scatter + Chemical dye method for WBC 5-part differential analysis and WBC counting

Parameters

25 parameters: WBC, Lym%, Mon%, Neu%, Bas%, Eos%, Lym#, Mon#, Neu#, Eos#, Bas#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT, P-LCR, P-LCC.

24 research parameters including LIC%, LIC#, ALY%, ALY#, PLT Clump#, PLT Clump%, Lip#, Lip%, NRBC#, NRBC%, Blast#, Blast%, PDW-SD, NLR, PLR, Neu-X, Neu-Y, Neu-Z, Lym-X, Lym-Y, Lym-Z, Mon-X, Mon-Y, Mon-Z

3 histograms for WBC, RBC and PLT

4 scattergrams for WBC differential

Reagent

M-52D Diluent, M-52DIFF Lyse, M-52LH Lyse, Probe Cleanser

Performance

Parameter	Linearity Range	Precision	Carryover
WBC	0-500×10 ⁹ /L	≤2% (4-15×10 ⁹ /L)	≤0.5%
RBC	0-8×10 ¹² /L	≤1.5% (3.5-6.0×10 ¹² /L)	≤0.5%
HGB	0-250g/L	≤1.5% (110-180g/L)	≤0.6%
PLT	0-5000×10 ⁹ /L	≤6.0% (100-149×10 ⁹ /L) ≤4.0% (150-500×10 ⁹ /L)	≤1.0%

Sample Volume

Prediluted mode	20 µL
Whole blood mode	15 µL
Capillary whole blood mode	15 µL

Throughput

60 samples per hour

Display

10.4 inch TFT Touch Screen

Multi-language

Chinese, English, Spanish, Portuguese, Russian, French, Bahasa Indonesia

Data Storage Capacity

Up to 250,000 results including numeric and graphical information

Communication

LAN port supports HL7 protocol

Interface

USB, LAN

Support bi-directional LIS

Printout

External Thermal printer / Laser printer / Inkjet printer, various printout formats and user-defined formats

Operating Environment

Temperature: 10°C~30°C

Humidity: 20%~85%

Air pressure: 70 kPa~106 kPa

Power requirement

100V-240V

50Hz/60Hz

Dimension and Weight

Depth(400 mm) x width(320 mm) x height(410 mm)

Weight :24kg

DIAMOND[®]

DIAGNOSTICS



SmartLyte[®]

The World's Most Reliable Electrolyte Analyzer



SmartLyte®

The World's Most Reliable Electrolyte Analyzer

Sample

Whole Blood, Serum, Plasma, Urine or Dialysate

Sample Size

95 µl

Number of Parameters

3 (Simultaneously)

Detection Range

Blood Na⁺: 40-200 mmol/L

Dialysate K⁺: 1.7-15 mmol/L

Cl⁻: 50-200 mmol/L

Ca⁺⁺: 0.3-5.0 mmol/L

Li⁺: 0.2-5.5 mmol/L

Urine Na⁺: 3-300 mmol/L

K⁺: 5-120* mmol/L

Cl⁻: 15-300 mmol/L

*60-120 requires additional dilution

Reproducibility

Typical Within Run (n=30)

Blood, Serum, Plasma, Dialysate

Na⁺: CV ≤ 1% (120-160mmol/L)

K⁺: CV ≤ 2% (2.5-6 mmol/L)

Cl⁻: CV ≤ 2% (85-130 mmol/L)

Ca⁺⁺: SD ≤ 0.02 mmol/L (0.8-1.5 mmol/L)

Li⁺: SD ≤ 0.02 mmol/L (0.4-1.3 mmol/L)

(Lithium not typically measured in dialysate samples)

Urine

Na⁺: CV ≤ 5% (100-250 mmol/L)

K⁺: CV ≤ 5% (10-60 mmol/L)

Cl⁻: CV ≤ 5% (100-250 mmol/L)

(Calcium and Lithium are not typically measured in urine samples)

Display Resolution

Na⁺: 1 mmol/L or 0.1 mmol/L

K⁺: 0.1 mmol/L or 0.01 mmol/L

Cl⁻: 1 mmol/L or 0.1 mmol/L

Ca⁺⁺: 0.01 mmol/L or 0.001 mmol/L

Li⁺: 0.01 mmol/L or 0.001 mmol/L

Veterinary Options

Feline, Canine, Bovine, Equine, Swine, Ovine or Open

This analyzer is produced and distributed by Diamond Diagnostics Inc. There is no affiliation, connection, sponsorship or association between Diamond Diagnostics Inc. and Roche Diagnostics.



Analysis Time

60 sec without printout (60 per hour)

72 sec with printout (50 per hour)

Data Storage

1000 Patient Results

500 Level 1 QC Results

500 Level 2 QC Results

500 Level 3 QC Results

Calibration

2 Point every 4 hours

On Demand

1 Point after every Measurement

User Input

Keypad, External Keyboard

External Barcode Scanner (optional)

Output

Graphic backlit display

Graphic 16 column printer

RS232 LIS Communication

Ambient Conditions

15-32°C, Room temperature (60-90°F)

<85% humidity

Languages

English, Chinese, French, German, Italian, Korean
Japanese, Portuguese, Russian, Spanish, Polish

Power

100-240V ~ 50/60 Hz (self adjusting)

1.6 A max, 50 Watts max

Size & Weight

13.2 x 12.4 x 12" or 335 x 315 x 295 mm

14 lbs or 6 kgs

DIAMOND®
D I A G N O S T I C S

333 Fiske Street, Holliston, MA 01746
Tel: 508-429-0450 | Fax: 508-429-0452
www.diamonddiagnostics.com

SOP23-0020F REV09 08/11/17

Features

• Built-in incubator
• Automatic stirring system
• Five points calibration
• Accurate measurement without influence from pathological sample during the test
• Open system for reagent, low reagent consumption (50µl-100µl)
• Automatic storage, printout calculation parameter curve
• Large memory and review system
• User friendly software

Assay Report Specifications

• Prothrombin Time
• Activated Partial Thromboplastin Time
• Thrombin Time
• Fibrinogen Concentration
• Clotting factors are expressed in the of time (sec.), ratio or INR

Technical Specifications

Item	CA-01	CA-02
Channel	Single	Double
Built-in Incubator	37°C±0.2°C, capacity for 16 sample positions and 2 reagent positions.	37°C±0.2°C, capacity for 2×16 sample positions and 2×2 reagent positions.
Measuring System	Photometric	
Beam Source	LED	
Magnetic Stirring Motor	For measuring cuvette	
Data Input	Membrane keypad	
Display	Back—illuminated LCD	
Printer	Built-in thermal printer	
Operation Language	English, other languages on request	
Power Supply	AC 110V 60Hz / 220V 50Hz	
Dimensions	30cmx35cmx15cm	30cmx35cmx15cm
Weight	4.0kgs	4.0kgs

CLINDIAG...

The Reference for Quality and Service

CLINDIAG



CA-01/02

Coagulometer



ISO9001:2008 & ISO13485:2003

H-500

Urine Analyzer



DIRUI H-500 Semi-automatic urine analyzer's outstanding performance proves itself to be a reliable friend for medium laboratories.

Product features:

- ◎ Large touch screen is convenient for users' operation
- ◎ Built-in thermal printer can print results automatically
- ◎ Waste box can collect waste strips automatically
- ◎ 4 wavelength cold light source ensure the result accuracy
- ◎ High throughput is 420 samples/hour
- ◎ 14 test items are optional
- ◎ Large capacity of data memory is convenient for review

Order Information:

Product Number	Description	Pack Size
1520104001	DIRUI H-500 Urine Analyzer	1 instrument

Product Number	Description	Volume	Pack Size
2310201003	DIRUI H8	100 strips/ bottle	1 bottle
2310201002	DIRUI H10	100 strips/ bottle	1 bottle
2310201001	DIRUI H11	100 strips/ bottle	1 bottle
2310201021	DIRUI H11-MA	100 strips/ bottle	1 bottle
2310201037	DIRUI H13-Cr	100 strips/ bottle	1 bottle
2310201089	DIRUI H14-Ca	100 strips/ bottle	1 bottle

H-100

Urine Analyzer



DIRUI H-100 Semi-automatic urine analyzer offers ideal urine analysis solutions for small laboratories and hospitals.

Product features:

- ◎ Friendly interface is convenient for users' operation
- ◎ Built-in thermal printer can print results automatically
- ◎ 4 wavelength cold light source ensure the result accuracy
- ◎ Throughput is 60 samples/hour or 120 samples/hour
- ◎ 14 test items are optional
- ◎ Large capacity of data memory is convenient for reviewing
- ◎ H-100 can connect computer with RS-232

Order Information:

Product Number	Description	Pack Size
1520102001	DIRUI H-100 Urine Analyzer	1 instrument

Product Number	Description	Volume	Pack Size
2310201003	DIRUI H8	100 strips/ bottle	1 bottle
2310201002	DIRUI H10	100 strips/ bottle	1 bottle
2310201001	DIRUI H11	100 strips/ bottle	1 bottle
2310201021	DIRUI H11-MA	100 strips/ bottle	1 bottle
2310201037	DIRUI H13-Cr	100 strips/ bottle	1 bottle
2310201089	DIRUI H14-Ca	100 strips/ bottle	1 bottle

Urinalysis Control



Urinalysis Control is original reagent from DIRUI, which can monitor both urine strips and urine analyzer`s status. Urinalysis Control offers UBG.BIL.KET.BLD.PRO.NIT.LEU.GLU.SG.PH.MALB.Cr .Ca totally 13 items.

Product features:

- © Liquid reagent without dissolution can be used directly to avoid manual sampling error
- © Free from material extracted from human urine to avoid the potential infection
- © The reagents are all non-toxic and environment friendly

Product Number	Description	Volume	Pack Size
2320701001	Urinalysis Control (Positive)	8ml/bottle	4 bottles
2320702001	Urinalysis Control (Negative)	8ml/bottle	4 bottles

DIRUI URINALYSIS STRIPS COLLECTION

Product Number	Urinalysis Strip Description	Use Method	Urine Analyzer	Test Parameters														Packing
				Leucocytes	Nitrite	Urobilinogen	Protein	pH	Blood	SG	Ketone	Bilirubin	Glucose	Ascorbic acid	Microalbumin	Creatinine	Calcium	
2310201093	DIRUI H14-Ca(H-800)	Reader & Visual	H-800(DIRUI)	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	100 strips/bottle
2310201106	DIRUI H13-Cr(H-800)	Reader & Visual	H-800(DIRUI)	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	
2310201089	DIRUI H14-Ca	Reader & Visual	H-100/H-300/H-500 (DIRUI)	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	
2310201037	DIRUI H13-Cr	Reader & Visual	H-50/H-100/H-300/H-500 (DIRUI)	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	
2310201022	DIRUI H12-800MA	Reader & Visual	H-800(DIRUI)	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙			
2310201025	DIRUI H10-800	Reader & Visual	H-800(DIRUI)	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙					
2310201024	DIRUI H11-800	Reader & Visual	H-800(DIRUI)	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙				
2310201021	DIRUI H11-MA	Reader & Visual	H-100/H-300/H-500 (DIRUI)	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙		⊙			
2310201001	DIRUI H11	Reader & Visual	H-100/H-300/H-500 (DIRUI)	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙				
2310201027	DIRUI M10	Reader & Visual		⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙					
2310201020	DIRUI E10	Reader&Visual		⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙					
2310201002	DIRUI H10	Reader & Visual	H-50/H-100 (DIRUI)	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙					
2310201004	DIRUI A10	Reader & Visual		⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙					
2310201006	DIRUI 9 ITEMS	Visual	N/A		⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙					
2310201007	DIRUI 8 ITEMS	Visual	N/A			⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙					
2310201008	DIRUI 5 ITEMS(PRO,pH,BLD,KET,GLU)	Visual	N/A				⊙	⊙	⊙		⊙		⊙					
2310201009	DIRUI 4 ITEMS(PRO,pH,SG,GLU)	Visual	N/A				⊙	⊙		⊙			⊙					
2310201010	DIRUI 4 ITEMS(PRO,pH,BLD,GLU)	Visual	N/A				⊙	⊙	⊙				⊙					
2310201011	DIRUI 3 ITEMS(PRO,pH,GLU)	Visual	N/A				⊙	⊙					⊙					
2310201013	DIRUI 2 ITEMS(KET,GLU)	Visual	N/A								⊙		⊙					
2310201081	DIRUI 2 ITEMS(PRO,GLU)	Visual	N/A				⊙						⊙					
2310201019	DIRUI 1 ITEMS(PRO)	Visual	N/A				⊙											
2310201018	DIRUI 1 ITEMS(KET)	Visual	N/A								⊙							
2310201016	DIRUI 1 ITEMS(GLU)	Visual	N/A										⊙			⊙		
2310201091	DIRUI H2-Cr	Visual	N/A												⊙			



H-100

Urine Analyzer



DIRUI

H-100

Urine Analyzer

Product Characteristics:

- Adopting the advanced high luminosity cold light source with 4 -wavelength, which improves the sensitivity, accuracy, specificity, and reduces the interference from ambient light
- Adopting automatic waste handling system, which avoids cross-contamination between samples
- Built-in thermal printer with high speed and low noise; External stylus printer
- Connectable with DIRUI urine sediment analyzer
- Users can set an abnormal value flag by themselves
- International, regular and symbol system units display for option



Technical Specification:

- Test items: urobilinogen, bilirubin, ketone, Creatinine, Micro-albumin, blood, protein, nitrite, leukocytes, glucose, specific gravity, pH and VC, Ca.
- Test wavelength: 525nm, 572nm, 610nm, 660nm
- Test principle: Photoelectric colorimetry
- Suitable strips: DIRUI H8, H10, H11, H11-MA, Urinalysis strips
- Test throughput: 120 strips/h or 60 strips/h optional
- Data storage: 5000 patient results
- Computer interface: RS-232 port; parallel printer interface
- Display: 240×64 dot-matrix LCD
- Language: Chinese, English, Russian, Polish, Italian, Spanish, Portuguese, Turkish, German, French
- Power supply: ~100-240V, 50Hz/60Hz
- Power: 40VA
- Dimensions: 385mm×337mm×166mm(L×W×H)
- Weight: 3.9kg
- Printer: Built-in thermal printer



Certified to
ISO 9001:2008 and ISO 13485:2003

DIRUI INDUSTRIAL CO., LTD.

3333 Yiju Street, New&High Tech. Development Zone
Changchun, Jilin 130103, P.R. China
Tel: +86(431)81935329 85100409
Fax: +86(431)85172581 85083741
E-mail: dirui@dirui.com.cn Http://www.dirui.com.cn
·Specifications subject to change without notice.

20170508

DIRUI



H-500
Urine Analyzer



DIRUI

H-500

Urine Analyzer

Product Characteristics:

- Adopting the advanced high luminosity cold light source with 4 -wavelength, which improves the sensitivity, accuracy, specificity, and reduces the interference from ambient light
- Adopting automatic waste handling equipment, which avoids cross-contamination between samples
- Automatically rectify the test results influenced by non-specificity, pH, specific gravity, and color
- Built-in thermal printer with high speed and low noise; External stylus printer
- Connectable with urine sediment analyzer
- Users can set an abnormal value flag by themselves
- International, regular and symbol system units available for option



Technical Specification:

- Test items: urobilinogen, bilirubin, ketone, blood, protein, nitrite, leukocytes, glucose, specific gravity, pH and VC microalbumin creatinine, calcium
- Test wavelength: 525nm, 572nm, 610nm, 660nm
- Test principle: Photoelectric colorimetry
- Suitable strips: DIRUI H8, H10,H11 and H11MA(N) H12,H13-Cr,H14-Ca urinalysis strips
- Test throughput: 514strips/h
- Data memory: 5000 patient results
- Computer interface: RS-232 port; parallel printer interface
- Display: 5.7" LCD
- Language: Chinese,English,Russian,Polish,Italian,Spanish,Portuguese, Turkish,Hungarian,German,French
- Power supply: 100~240VAC, 50Hz/60Hz
- Power: 40VA
- Dimensions: 395mm×382mm×304mm
- Weight: 7.4kg
- Printer: Built-in thermal printer



Certified to
ISO 9001:2008 and ISO 13485:2003

DIRUI INDUSTRIAL CO.,LTD.

3333 Yiju Street,New&High Tech. Development Zone
Changchun,Jilin 130103,P.R.China
Tel: +86(431)81935329 85100409
Fax: +86(431)85172581 85083741
E-mail: dirui@dirui.com.cn Http://www.dirui.com.cn
·Specifications subject to change without notice.

20160902

DIRUI

Features

- Easy operation by one button.
- End point, kinetic, fixed time, multistandard, bichromatic, etc.
- Filter wavelengths: 340/405/492/510/546/578/620nm, 2 more open filter positions, others on request.
- With 20 incubating positions.
- Large memory to store 200 test programs and 1000 test results.
- Excellent Q.C function, Q.C chart can be stored, displayed and printed.
- 3 levels temperature: 25°C, 30°C, 37°C can be selected in flow cell and incubator.
- Real time graph can be displayed and printed.

Technical Specifications

Model	SA-20
Reading Cuvette	Both through cell and direct reading cuvette
Incubating Positions	20 incubating positions
Photometric System	Light source: 6V, 10 W longlife halogen lamp
	Filters: 340/405/492/510/546/578/620nm, 2 more open filter positions, ± 2 nm pass-hand
Measuring System	Wavelength accuracy: ± 2 nm
	Measuring range: 0-2.500 O.D.
	Photometric linearity: $\pm 2\%$ from 0 to 2.000 O.D.
	Photometric accuracy: $\pm 2\%$ from 0 to 2.000 O.D.
Incubator Temperature	Drift < 0.005 O.D.
	Carry over $\leq 1\%$
	25°C, 30°C, 37°C RT
Control	Precision: $\pm 0.1^\circ\text{C}$
Display	5 inch colorful touch screen
Printer	Built-in thermal printer
Connection Port	RS-232 & USB
Power Supply	AC 110V 60Hz / 220V 50Hz
Dimensions	34cmX38cmX18cm
Weight	8.5kg

CLINDIAG...

The Reference for Quality and Service

CLINDIAG



SA-20

Chemistry Analyzer



ISO9001:2008 & ISO13485:2003



CLINDIAG SYSTEMS CO., LTD

Add: #29 Zhiyuan Road, Jurong Economic Development Zone, Zhenjiang, Jiangsu, China
Tel: 0086-0511-80775555
Fax: 0086-0511-80770077
Website: <http://www.clindiag.com>

UK Office

CLINDIAG SYSTEMS (UK) CO., LTD
Add: 35 Ivor Place Lower Ground London
England NW1 6EA
E-mail: marketing@clindiag.com

U.S. Office

Add: 1351 S. Leavitt Ave, # 104 Orange City, Florida 32763 USA
Tel: 001 386 456 1235
Fax: 001 386 456 1237
E-mail: info@clindiagusa.com

India Office

Add: B-1177-78, G.D. Colony Mayur Vihar Phase-III, Delhi-110096
PH: 0091 11 22618779
Fax: 0091 11 22618780
E-mail: contact@clindiagindia.com

The logo for Saver One, featuring the word "Saver" in blue, a red heart symbol, and the word "One" in blue. A registered trademark symbol (®) is located at the top right of the word "One".

Saver One[®]

Complete **AEDs** range to **save lives**.



**life is a breath,
...keep it safe with us**

www.amiitalia.com

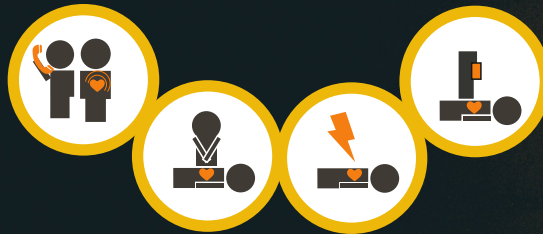
THE IMPORTANCE OF AEDs TO BEAT/WIN SCA

Sudden cardiac arrest is unpredictable; it can happen anywhere, anytime, at any age and without any warning. For each minute that passes by the probability of survival drops of 7/10%. Time is crucial in these situations and using an AED might be the only effective action.

EACH 2 SECONDS SUDDEN CARDIAC ARREST **CLAIMS 1 LIFE !!** TO ANYONE, ANYWHERE

A life- threatening condition that can be reversible just thanks to a timely defibrillation.

CHAIN OF SURVIVAL



THE KEY IS TO UNABLE AVAILABILITY AND EASY ACCESS TO AEDs

SPORT FACILITIES:



Regardless of the discipline performed, AED provision should be mandatory for professional, semi-professional and amateur sports.

COMMUNITIES:



A lack of confidence in using an AED and the inability to locate a nearby device is a missed opportunity to save lives! Governments should strongly advocate for public access defibrillation programs; every citizen could be trained and then become a potential first responder to a SCA.

WORKPLACES:



As the chances of surviving a cardiac arrest are increased if the emergency treatment is provided promptly, AED provision is highly recommended to any work places that aims to an health and safe enviroment.



HOSPITALS:

ERC guidelines says “...staff should be trained to enable achievement of the goal of providing the first shock within 3 minutes of collapse anywhere in the hospital”



SCHOOLS:

AEDs are easy to use: by following the simple and clear voice prompts bystanders can perform all the crucial steps that can save lives. Furthermore several studies indicate that students without any CPR/AED training can use an AED as instructed.

SaverOne®



Saver One[®]

everywhere for life

Sudden Cardiac Arrest can happen anytime, anywhere and without warning.
The person affected has only few precious minutes left for a chance of survival.
YOUR FIRST AID COULD BE SOMEBODY'S LAST CHANCE

SAVER ONE AEDs are designed for a public access use and licensed to administer fast and safe rescues.
Highly-effective and user-friendly for any lay rescuer, even without minimal training.

SAVER ONE Semi and Fully Automatic defibrillators are two dependable members of our AED family.
The Fully Automatic administers a defibrillating shock (when appropriate) with no shock button for the user to press whilst the Semi-Automatic administers a shock at the press of a button.

Choose the best portable AED that's right for you to save lives everywhere in any public circumstance (home, office, school, hotel, airport, train, beach, gym, pool, disco, etc.) and before EMS team arrives.

Automated testing to vouch daily functionality

A **new look** complete with all pictograms which light up to guide rescuers step by step

More alternatives for recording and transfer data: **internal memory**, removable **card**, **USB**

Slight yet solid with **long-lasting battery options** to ensure the best portability in any circumstance

Biphasic technology **up to 360J energy**

Unique features combined with available configurations give rise to exclusive devices



SEMI-AUTOMATIC two buttons

Meet AHA/ERC 2017 Guidelines

Saver One[®]

Maintenance-Free: Automatically performs daily, monthly and six-month extensive self-checks of all main components: battery, internal electronics, energy charge and disarm, shock and ECG calibration systems. Daily testing data are stored by the device as text file (named AED1LOG) easily readable by any computer.
AED runs further tests after each battery insertion as well as every time the device is turned on.
A visual cue (green/red status indicator) provides effective alert to users whether AED is in working order and ready for a rescue.

Service Mini-Screen: The mini LCD screen always displays a battery gauge with its residual percentage charge, error codes in faulty conditions, text prompts in accordance with audible voice instructions helpful in noisy and chaotic environments.

INFO button: The "i" button provides valuable device/battery technical information and enable to change the language

CPR Coaching: More instructive voice and text prompts guide user through rescue. A built-in metronome assist responder during the CPR, providing audio cues for the appropriate number and rate of chest compressions.

Adult/Child capability: after connecting pads to the patient, flashing icons on the keyboard display which pads are in use (adult/pediatric). Devices senses when pediatric pads are installed and adjusts to use the appropriate lower energy level (50J).

DEFIBRILLATOR

Operation:	Semi-Automatic Version Fully Automatic Version
Energies:	Standard max 200J or Power max 360J
Waveform:	Adaptive BTE (biphasic truncated exponential) conforming to patient chest's impedance
Protocols:	Various adult shock protocols available on request
Factory default:	Adult Standard escalating 150, 200, 200J Adult Power escalating 200, 250, 360J Pediatric (Standard or Power) 50J fixed
Charging time:	≤ 9 seconds with a new and fully charged battery depleted battery will result in a longer charging time
Analysis time:	IEC/EN 60601-2-4 from 4 to 15 seconds
Impedance:	20-200 ohms
Sensitivity:	IEC/EN 60601-2-4 (AHADB, MITDB source), 97%
Specificity:	IEC/EN 60601-2-4 (AHADB, MITDB source), 99%
Controls:	3 buttons for Semi-Automatic: ON/OFF, Shock "i" info button 2 buttons for Automatic: ON/OFF, "i" info button
Flashing Icons:	"connects pads to patient" "adult/child" informing on pads type use "don't touch patient" warning to stay clear "touch patient" informing it's safe to touch
Indicators:	Status LED indicator informing on device condition Battery gauge with remaining capacity rate Audible alerts and text display with service alarms
Upgradeable:	through a USB cable or memory card



FULLY AUTOMATIC one button

MODEL NUMBERS

Code SVO-B0001: Semi-Automatic Standard Version at 200J
Code SVO-B0002: Semi-Automatic Power Version at 360J

Code SVO-B0847: Fully Automatic Standard Version at 200J
Code SVO-B0848: Fully Automatic Power Version at 360J

CONFIGURATION OPTIONS (Box Contents)

Conf-Norm:	Standard Basic Configuration (adult pads, disposable battery, carrying case)
Conf-Rech:	Rechargeable Configuration (adult pads, accumulator, charger station, carrying case)

BATTERY OPTIONS

Type:	Li-SOCI2 Disposable, code SAV-C0903
Autonomy:	300 complete rescue cycles (shocks at 200J and CPR) or 200 complete rescue cycles (shocks at 200J and CPR) or 35 hours ECG Monitoring for a new and fully charged battery (*)
Shelf-Life:	when stored in original packaging 5 years (*)
Battery-Life:	4 years once installed to AED, assuming one battery insertion test and daily self-test but without switching AED on (*)

Type:	Li-ion Accumulator, code SAV-C0011
Recharging time:	2,5 hours with the charger station code SAV-C0014 (*) (recommended to charge every 4 months at least)
Autonomy:	250 shocks at 200J or 150 shocks at 360j or 21 hours in ECG Monitoring for a new fully charged accumulator (*)
Battery-Life:	2 years or 300 charging cycles (*)

PADS OPTIONS

Type:	Disposable, pre-gelled and self-adhesive
Adult:	Code SAV-C0846, for patient >8 years or >25 kg
Pediatric:	Code SAV-C0016, for patient <8 years or <25 kg
Cable lenght:	120 cm
Shelf-Life:	30 months

EVENT RECORDING

Internal memory:	up to 6 continuous hours of ECG and rescue events.
Memory capacity:	6 hours of audio, ECG and events
Optional memory:	Removable SD card, Length of storage depends on card capacity: a 2GB card records up to 100 hours
Data recording:	"AED1LOG" text file with detailed self-test activity "AEDFILES" with complete recorded events
Event review:	"Saver View Express" data manager software

PHYSICAL

Size:	26,5 x 21,5 x 7,5 cm 1,95 kg with disposable battery 2,10 kg with rechargeable battery
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ENVIRONMENTAL

Operating temperature:	0°C to 55°C (32°F TO 131°F)
Storing/Shipping temperature:	-40°C to 70°C (-40°F TO 158°F) without battery
Humidity:	10% to 95% relative humidity non condensing
Sealing (IP Protection):	IEC/EN 60529 class IP54; splash proof, dust protected
Shock/Drop Abuse Endurance:	IEC/EN 60601-1 clause 21; 1 meter drop, impact, force, rough handling, mobile tolerance
Electrostatic Discharge:	IEC/EN 61000-4-2
Electromagnetic Compatibility:	IEC/EN 60601-1-2 Emission, Immunity
Electrical Protection:	IEC/EN 60601-1 class I type BF
Directive	
93/42/CEE and 2007/47/CE:	Class IIb

(*)Temperature at 20°C Humidity 45% non-condensing

6 YEARS WARRANTY

Manufactured in Italy



Saver One D

the AED goes beyond

SAVER ONE D is a rugged, small and lightweight **AED** with **ECG Monitoring** capability. Totally reliable for trained users featuring advanced capacities to help improve lifesaving outcomes.

THE RIGHT CHOICE FOR HARSH, OUTDOOR OR MOBILE USE

While in AED mode, it allows the user to view the ECG and everything needed to know about the patient and ongoing rescue treatment on a very large (12x8 cm) full-color interactive display. Additionally the SAVER ONE D can be switched in a ECG Monitoring mode, to allow for watch over the rhythm and heart rate while using defibrillation pads or standard ECG electrodes connected to a separate cable.

Great graphical interface combined with instructive voice prompts to guide rescuers

Functionality ensured by **automatic daily self-test**

Slight yet solid with **long-lasting battery options** to ensure the best portability in any circumstance

More alternatives for recording and transfer data: **internal memory**, removable **card**, **USB**, and **IrDA Port** optional with Print Configuration

Biphasic technology **up to 360J energy**

Unique features combined with available configurations give rise to exclusive devices

Meet AHA/ERC 2017 Guidelines



AED ECG Monitoring

Saver One D

Maintenance-Free: Automatically performs daily, monthly and six-month extensive self-checks of all main components: battery, internal electronics, energy charge and disarm, shock and ECG calibration systems. Daily testing data are stored by the device as text file (named AED1LOG) easily readable by any computer. AED runs further tests after each battery insertion as well as every time the device is turned on. A visual cue (green/red status indicator) provides effective alert to users whether AED is in working order and ready for a rescue.

Service Mini-Screen: In standby the mini LCD screen displays a check mark confirming AED is ready for use and a battery gauge informing about the residual charge. Error codes will appear in faulty conditions.

Helpful Menu: 3 buttons for navigating the software menu to set up device at user leisure: adjust the local date or time, adapt the screen or volume to ambient lights and noises, exclude the microphone while recording events, select a different language, print out the ECG files or simply get information on device and battery.

CPR Coaching: More instructive voice and text prompts guide user through rescue. A built-in metronome assist responder during the CPR providing audio cues for the appropriate number and rate of chest compressions.

Adult / Child Capability: Can be used on patients of any age with Adult or Pediatric proper electrodes. Device senses when Pediatric pads are installed and automatically adjusts to use a more appropriate lower energy level (50J).

Monitoring section menu: a new section has been introduced for the management of technical and physiological alarms and signals, according to IEC/EN 60601-2-27: patient loss, high or low heart rate, audio and visual signal for detection of a shockable rhythm so that the operator can switch/active one of the available modes to deliver the shock (using the appropriate pads); scaling of the ECG trace on the display (gain x2 or /2) reset of the audio or visual alarms..

DEFIBRILLATOR

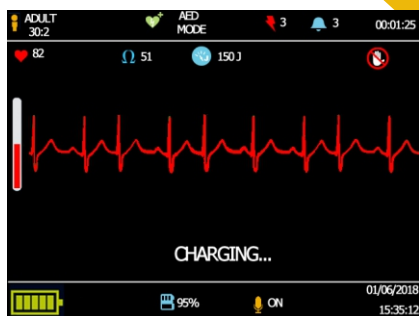
Operation:	AED Semi-Automatic ECG Monitoring capability
Energies:	Standard max 200J or Power max 360J
Waveform:	Adaptive BTE (biphasic truncated exponential) conforming to patient chest's impedance
AED Protocols:	Various adult shock protocols available on request
Factory default:	Adult Standard escalating 150, 200, 200J Adult Power escalating 200, 250, 360J Pediatric (Standard or Power) 50J fixed
Charging time:	≤ 9 seconds with a new and fully charged battery depleted battery will result in a longer charging time
Analysis time:	IEC/EN 60601-2-4 from 4 to 15 seconds
Impedance:	20-200 ohms
Sensitivity:	IEC/EN 60601-2-4 (AHADB, MITDB source), 97%
Specificity:	IEC/EN 60601-2-4 (AHADB, MITDB source), 99%
Controls:	2 buttons: ON/OFF, shock button, and 3 buttons to surf the menu.
Indicators:	Status LED indicator informing on device condition Battery Gauge with remaining capacity rate Audible alerts and text display with service alarms
Upgradeable:	through a USB cable or memory card

ECG MONITORING

Operations:	Through defibrillation pads or standard ECG electrodes attached to a separate 2-Lead patient monitoring reusable cable SAV-C0017
ECG size:	Manual setting through the menu
Heart Rate:	30-300 bpm
Sweep Speed:	25 mm/sec
Standard:	IEC/EN 60601-2-27 less then the points 202.6.2.101; 201.12.1.101.12,13; 208.6.6.2.101 not performed for the intended use of the device, as it is not intended for environments such as operating theaters or intensive care units
Display:	5,7" TFT color, 640 x 480 pixel

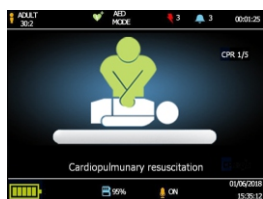
5.7" TFT Color Display

the most detailed and comprehensive screen provides valuable information to rescuers running text and interactive graphics combined with voice messages



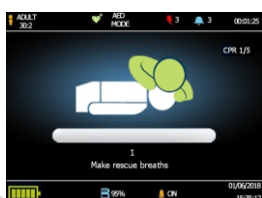
ABOUT DEVICE:

a **battery gauge** with residual capacity the indicator of **available memory** for recording a notice if the **microphone** is active or OFF the local **date and time**



ABOUT RESCUE:

the adult or child **protocol in use** the **modality in use** (AED or ECG) the **fibrillation and shock counts** the elapsed **rescue time** the **heart rate** (bpm) the **impedance** (ohms) the **ECG waveform** a **touch/not touch** pictogram a **charging bar graph** if device charges the **energy level** to be delivered (joule) a **CPR bar graph** as countdown a **CPR cycles count**



BATTERY OPTIONS

Type:	Li-SOCI2 Disposable, code SAV-C0903
Autonomy:	250 complete rescue cycles (shocks at 200J and CPR) or 160 complete rescue cycles (shocks at 360J and CPR) or 24 hours ECG Monitoring for a new and fully charged battery (*) when stored in original packaging 5 years (*)
Shelf-Life:	
Battery-Life:	4 years once installed to AED, assuming one battery insertion test and daily self-test but without switching AED on (*)
Type:	Li-ion Accumulator, code SAV-C0011
Recharging time:	2,5 hours with the charger station code SAV-C0014 (*) (recommended to charge every 4 months at least)
Autonomy:	200 shocks at 200J or 110 shocks at 360J or 14 hours in ECG Monitoring for a new fully charged accumulator (*)
Battery-Life:	2 years or 300 charging cycles (*)

PADS OPTIONS

Type:	Disposable, pre-gelled and self-adhesive
Adult:	Code SAV-C0846, for patient >8 years or >25 kg
Pediatric:	Code SAV-C0016, for patient <8 years or <25 kg
Cable lenght:	120 cm
Shelf-Life:	30 months

EVENT RECORDING

Internal memory:	up to 6 continuous hours of ECG and rescue events.
Memory capacity:	6 hours of audio, ECG and events
Optional memory:	Removable SD card, Length of storage depends on card capacity: a 2GB card records up to 100 hours
Data recording:	"AED1LOG" text file with detailed self-test activity "AEDFILES" with complete recorded events
Event review:	"Saver View Express" data manager software

PHYSICAL

Size:	26,5 x 21,5 x 7,5 cm 2,30 kg with disposable battery 2,45 kg with rechargeable battery
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ENVIRONMENTAL

Operating temperature:	0°C to 55°C (32°F TO 131°F)
Storing/Shipping temperature:	-40°C to 70°C (-40°F TO 158°F) without battery
Humidity:	10% to 95% relative humidity non condensing
Sealing (IP Protection):	IEC/EN 60529 class IP54; splash proof, dust protected
Shock/Drop Abuse Endurance:	IEC/EN 60601-1 clause 21; 1 meter drop, impact, force, rough handling, mobile tolerance
Electrostatic Discharge:	IEC/EN 61000-4-2
Electromagnetic Compatibility:	IEC/EN 60601-1-2 Emission, Immunity
Electrical Protection:	IEC/EN 60601-1 class I type BF
Directive	
93/42/CEE and 2007/47/CE:	Class IIb

MODEL NUMBERS

Code SVD-B004:	Standard Version with maximum energy at 200J
Code SVD-B005:	Power Version with maximum energy at 360J

CONFIGURATION OPTIONS (Box Contents)

Conf-Norm:	Standard Basic Configuration (adult pads, disposable battery, carrying case)
Conf-Rech:	Rechargeable Configuration (adult pads, accumulator, charging station, carrying case)
Conf-Print:	Print Ready Configuration (adult pads, disposable battery, carrying case, IrDA port and thermal printer)
Conf-Rech/Print:	Rechargeable & Print Ready Configuration (adult pads, accumulator, charger station, carrying case, IrDA port and thermal printer)

(*) Temperature at 20°C Humidity 45% non-condensing

6 YEARS WARRANTY

Manufactured in Italy



Saver One P[®]

the handy PRO AED

SAVER ONE P is a tough, small and lightweight Defibrillator easy to carry and use anywhere and able to act as an **AED** or a Manual Defibrillator or a Basic Cardiac Monitoring device.

HIGHLY FLEXIBLE AND VERSATILE WITH ADVANCED CAPABILITIES

AED per default, reliable for any BLS rescuer, can be easily switched in a Manual Defibrillator giving to ALS responders the best decision-making control for a manual shock timing or an electric cardioversion (synchronised shock).

To meet ALS professionals, SAVER ONE P has been designed with all advanced key features to make fast and effective defibrillation everywhere and in any circumstance, even the hardest and has been equipped with a new widely manageable software program which gives users the total control of device to suit their needs. Practical and flexible with Advanced PBLIS feature enabling healthcare providers to use the 15:2 CV ratio when performing a Pediatric Basic Life Support, as required by Guidelines if more than one rescuer with a duty to respond.

Supreme graphical user interface and new tools to have **total control** of the defibrillator

Biphasic **escalating energy** from 50 to 360J

Slight yet solid with long-lasting battery options to ensure the **best outdoor and mobile use**

Functionality guaranteed by daily self-test

Wider connectivity with removable card, USB and IrDA Port optional with Print Configuration

Unique features combined with available configurations give rise to exclusive devices



Meet AHA/ERC 2017 Guidelines

Saver One P[®]

Maintenance-Free: Automatically performs daily, monthly and six-month extensive self-checks of all main components: battery, internal electronics, energy charge and disarm, shock and ECG calibration systems. Daily testing data are stored by the device as text file (named AED1LOG) easily readable by any computer.

AED runs further tests after each battery insertion and every time device is turned on.

A visual cue (green/red status indicator) provides effective alert to users whether AED is in working order and ready for a rescue.

Service Mini-Screen: In standby the mini LCD screen displays a check mark confirming AED is ready for use and a battery gauge informing about the residual charge. Will run error codes in faulty conditions.

Entirely Discretionary: 6 push-buttons allowing users to get the total control of defibrillator while in use: select the best modality, Manual Synchronous or Asynchronous or simply AED, to treat SCA according to events, take decision for shock anytime by choosing the right energy level to be delivered at each shock and get the device charged and ready to shock whenever needed or even disarm it in case defibrillation is not more required.

After shocks, the heart rhythm rate can be watched over using the same defibrillation pads or, in case of longer monitoring, by connecting standard ECG electrodes to a separate optional reusable cable.

Each step is conducted with the appropriate running features selected and set up in the device software by users.

Adult / Child Capability: Can be used on patients of any age with Adult or Pediatric proper electrodes. Device senses when Pediatric pads are installed and automatically adjusts to use a more appropriate lower energy level (50J).

Monitoring section menu: a new section has been introduced for the management of technical and physiological alarms and signals, according to IEC/EN 60601-2-27: patient loss, high or low heart rate, audio and visual signal for detection of a shockable rhythm so that the operator can switch/active one of the available modes to deliver the shock (using the appropriate pads); scaling of the ECG trace on the display (gain x2 or /2) reset of the audio or visual alarms..

AED
ECG Monitoring
MANUAL Override

DEFIBRILLATOR

Operation:	AED Semi-Automatic (default) ECG Monitoring Manual Asynchronous or Synchronous (used to convert atrial or ventricular tachyarrhythmias)
Energies:	Standard max 200J or Power max 360J
Waveform:	Adaptive BTE (biphasic truncated exponential) conforming to patient chest's impedance
Energy type:	Escalating from 50 to 360J
AED Protocols:	Adult Standard escalating 150, 200, 200J Adult Power escalating 200, 250, 360J Pediatric (Standard or Power) 50J fixed (AED adult shock protocols can be customized)
Manual Protocol:	Selected by users from 50 to 360J. For electric cardioversion (in Synchronous mode) the shock is synchronised to occur with the R wave of the ECG.
Energy Display:	Screen provides the energy to deliver both in Manual mode or AED mode
Charging time:	≤9 seconds with a new and fully charged battery depleted battery will result in a longer charging time
Analysis time:	IEC/EN 60601-2-4 from 4 to 15 seconds
Impedance:	20-200 ohms
Sensitivity:	IEC/EN 60601-2-4 (AHADB, MITDB source), 97%
Specificity:	IEC/EN 60601-2-4 (AHADB, MITDB source), 99%
Controls:	2 buttons: ON/OFF, shock button; 3 buttons: to surf the menu; 3 buttons: select energy, charge, disarm the device
Indicators:	Status LED indicator informing on device condition Battery Gauge with remaining capacity rate Audible alerts and text display with service alarms through a USB cable or memory card
Upgradeable:	

ECG MONITORING

Operations:	Through defibrillation pads or standard ECG electrodes attached to a separate 2-Lead patient monitoring reusable cable SAV-C0017
ECG size:	Manual setting through the menu
Heart Rate:	30-300 bpm
Sweep Speed:	25 mm/sec
Standard:	IEC/EN 60601-2-27 less then the points 202.6.2.101; 201.12.1.101.12.13; 208.6.6.2.101 not performed for the intended use of the device, as it is not intended for environments such as operating theaters or intensive care units
Display:	5,7" TFT color, 640 x 480 pixel

BATTERY OPTIONS

Type:	Li-SOCI2 Disposable, code SAV-C0903
Autonomy:	250 complete rescue cycles (shocks at 200J and CPR) or 160 complete rescue cycles (shocks at 360J and CPR) or 24 hours ECG Monitoring for a new and fully charged battery (*)
Shelf-Life:	when stored in original packaging 5 years (*)
Battery-Life:	4 years once installed to AED, assuming one battery insertion test and daily self-test but without switching AED on (*)
Type:	Li-ion Accumulator, code SAV-C0011
Recharging time:	2,5 hours with the charger station code SAV-C0014 (*) (recommended to charge every 4 months at least)
Autonomy:	200 shocks at 200J or 110 shocks at 360J or 14 hours in ECG Monitoring for a new fully charged accumulator (*)
Battery-Life:	2 years or 300 charging cycles (*)

PADS OPTIONS

Type:	Disposable, pre-gelled and self-adhesive
Adult:	Code SAV-C0846, for patient >8 years or >25 kg
Pediatric:	Code SAV-C0016, for patient <8 years or <25 kg
Cable lenght:	120 cm
Shelf-Life:	30 months

EVENT RECORDING

Internal memory:	up to 6 continuous hours of ECG and rescue events.
Memory capacity:	6 hours of audio, ECG and events
Optional memory:	Removable SD card, Length of storage depends on card capacity: a 2GB card records up to 100 hours
Data recording:	"AED1LOG" text file with detailed self-test activity "AEDFILES" with complete recorded events
Event review:	"Saver View Express" data manager software

PHYSICAL

Size:	26,5 x 21,5 x 7,5 cm 2,30 kg with disposable battery 2,45 kg with rechargeable battery
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ENVIRONMENTAL

Operating temperature:	0°C to 55°C (32°F TO 131°F)
Storing/Shipping temperature:	-40°C to 70°C (-40°F TO 158°F) without battery
Humidity:	10% to 95% relative humidity non condensing
Sealing (IP Protection):	IEC/EN 60529 class IP54; splash proof, dust protected
Shock/Drop Abuse Endurance:	IEC/EN 60601-1 clause 21; 1 meter drop, impact, force, rough handling, mobile tolerance
Electrostatic Discharge:	IEC/EN 61000-4-2
Electromagnetic Compatibility:	IEC/EN 60601-1-2 Emission, Immunity
Electrical Protection:	IEC/EN 60601-1 class I type BF
Directive	
93/42/CEE and 2007/47/CE:	Class IIb

MODEL NUMBERS

Code SVP-B0006:	Standard Version with maximum energy at 200J
Code SVP-B0007:	Power Version with maximum energy at 360J

CONFIGURATION OPTIONS (Box Contents)

Conf-Norm:	Standard Basic Configuration (adult pads, disposable battery, carrying case)
Conf-Rech:	Rechargeable Configuration (adult pads, accumulator, charger station, carrying case)
Conf-Print:	Print Ready Configuration (adult pads, disposable battery, carrying case, IrDA port and thermal printer)
Conf-Rech/Print:	Rechargeable & Print Ready Configuration (adult pads, accumulator, charger station, carrying case, IrDA port and thermal printer)

(*) Temperature at 20°C Humidity 45% non-condensing

5.7" TFT Color Display
the most detailed and comprehensive screen
provides valuable information to rescuers
running text and interactive graphics
combined with voice messages

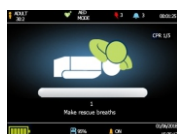
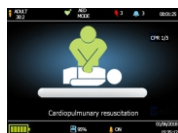


ABOUT DEVICE:

a **battery gauge** with residual capacity
the indicator of **available memory** for recording
a notice if the **microphone** is active or OFF
the local **date and time**, alarms.

ABOUT RESCUE:

the adult or child **protocol in use**
the **modality in use** (AED, ECG or Manual)
the **fibrillation and shock counts**
the elapsed **rescue time**
the **heart rate** (bpm)
the **impedance** (ohms)
the **energy level** to be delivered (joule)
a **touch/not touch** pictogram
the **ECG waveform**
the **R wave** detection in Manual Synchronous
a **charging bar graph** if device charges
a **CPR bar graph** and cycles countdown



6 YEARS WARRANTY

Manufactured in Italy



IMQ mark for
Safety & Quality

CE
0051

SAVER ONE AED Series supplies and accessories

Training Solutions



Saver One T code SVT-B0959

A smart and easy-to-use AED Trainer providing realistic training for many responders simultaneously.

Designed to meet needs of any instructor, it helps your responders learn to use defibrillators in simulated sudden cardiac arrest episodes for an extremely realistic training experience. A non-shocking unit that follows the 1, 2, 3-step operations of the Saver One defibrillator and guides responders, with voice prompts in various languages, from ECG analysis until shock and CPR. It is pre-configured with 10 realistic training scenarios manageable from distance with a wireless remote control and is equipped with a rechargeable battery which allows a 20 hours of continuous operating.



Both SAVER ONE T Versions come equipped with one set of adult reusable training pads, a remote control, an accumulator with its charger, a quick reference card, an user manual and a carrying case.

CPR Manikin

HALF- BODY TRAINING MANIKIN MAN-B0608/MAN-B1058

With acoustic indicator of the correct deepness of compression; a knob on the back with three different selection (adult-child-neutral) corresponding to 3 kinds of manikin resistance to compressions

Content:

- 1 CPR Simulator
- 1 User Manual & FAQ
- 6 Lungs & 2 Valves
- 1 Transport bag with MAT



BABY TRAINING TRAINING MANIKIN MAN-B1059/MAN-B1060

The most lifelike infant manikin suitable for performing correct infant CPR, performing realistic breathing and head tilt.



Content:

- 1 Practi-Baby
- 1 User manual
- 5 lungs and 2 valves
- 1 Transport bag

Fast Access Solution

NEW OUTDOOR CABINET:

- WITH ALARM
- WITH HEATING & ALARM (SAV-C1051)

Outdoor Wall Cabinet AMI ITALIA in polystyrene and ABS available with alarm or with heater & alarm
100% dust- and waterproof



NEW INDOOR CABINET:

- WITH ALARM (SAV-C0961)
- WITHOUT ALARM (SAV-C0912)

Indoor AMI ITALIA Wall Cabinet in strong metal, seamless look with or without audible alarm



10



WALL BRACKET (code SAV-C0911) & CARRYING CASE (code SAV-C0916)

Wall Mount Bracket in metal, designed for housing our AEDs in its carrying case.

Carrying case made of special shock proof and splashproof material, with adjustable shoulder strap and hook handle.



INDOOR CABINET: (code SAV-C1064)

Indoor Cabinet with customized video display

TOTEM STAND SUPPORT



To provide easy access and visibility to your AEDs for outdoor location.

SAV-C1062: Outdoor Metal Cabinet Yellow, With Heater And Alarm, Internal Light, Digital Display For Temperature.

SAV-C1063: Outdoor Metal Cabinet White and Green, With Heater And Alarm, Internal Light, Digital Display For Temperature

SAV-C1067: Column for Outdoor AED cabinet yellow SAV C1062

SAV-C1068: Column for Outdoor AED cabinet white and green SAV C1063

INDOOR CABINET: (code SAV-C1065 / C1066)

Indoor Cabinet Heart Shape Internal Cabinet with Alarm Colour White/Red (Batteries Not Included)



AED Wall Sign: (code SAV-C0997)

An AED Wall Sign hanging above a Wall Mount Bracket or Defibrillator Cabinet gives even greater visibility to the defibrillator.

ECG Monitoring & Data Management

2-Lead ECG Cable

(code SAV-C0017)

Suitable for SAVER ONE D and SAVER ONE P Defibrillators when used in ECG Monitoring mode. The alternative to pads in case of long-term monitoring to be connected to standard ECG electrodes.

8GB SD Card

(code SAV-C0907)

This removable card holds approximately 100 hours of events, ECG information and voice recording.

One card can hold data from multiple cases.

A flash data card reader enables data transfer from the card to a personal computer for use with the Saver View Express data management software.

Thermal Printer

(code SAV-C1070)

Works with SAVER ONE D and SAVER ONE P Defibrillators optioned with the Print Ready Configuration (Conf-Print).

Those are equipped with IrDA Port and therefore are able to communicate with this external thermal printer.

Data saved into device can be selected from the menu and print it out as ECG format complete with case details.



Saver View Express

(code SAV-C0019)

Saver View Express is a comprehensive data management tool for the most demanding professional allowing to view and manage on your PC patient data downloaded from defibrillators. With fully detailed data screen to record every aspect of the treatment, including response times, interventions, and rescuer observations.

Connecting Cable

(code SAV-C0158)

Spare connecting cable for Smart Simulator S1.

Simulator / Tester Smart Simulator S1

(code SSS-B0009)

This equipment can be used for a complete operating test of Saver One Defibrillators.

It comes with a dedicated cable to be plugged to any Saver One AED in order to let it run as it was a real lifesaving treatment.

Able to simulate several ECG rhythms (VF, VT, NSR, Asystole, etc.) and display the energy level discharged, up to 360J.



6 YEARS WARRANTY

Manufactured in Italy



IMQ mark for Safety & Quality



0051



IMQ mark for
Safety & Quality



North Italy Office
Viale Gran Sasso, 11
20131 Milano - Italy
Tel: +39.02.20509246
Fax: +39.02.29520839

South Italy Office & Production
Via Cupa Reginella, 15A
80010 Quarto - Italy
Tel: +39.081.8060574
Fax: +39.081.8764769

Headquarters production site:
A.M.I. International kft.
Kőzúzó u. 5/A 2000 Szentendre HU
Hungary
Tel. +3626302210