ENGLISH TRANSLATION

RISK ASSESSMENT (RISK ESTIMATION AND RISK EVALUATION) AND RISK REDUCTION

MACHINE: FFC BASE MACHINE

P/N: 0-528000-7

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INTRODUCTION

MANAGEMENT RESPONSIBILITIES:

The Management has specified as follows:

- the responsibility for carrying out the risk analysis is assigned to the technical office, which may seek advice from competent, independent companies/personnel.

- The responsibility for issuing the Risk Analysis document is assigned to the Technical Management.

- The risk analysis must be reviewed every time changes are made to the machine or new legislation, technical standards which could affect the safety of the product are issued, as well as in the event of an accident.

- Periodically review the feedback given by people who work on the field to ensure on-going suitability and effectiveness of risk management.

A –1.0 GENERAL INFORMATION

A 1.1 - FULL DESCRIPTION AND IDENTIFICATION OF THE MACHINE.

CRIMPING MACHINE FOR INTERCHANGEABLE MINI-APPLICATORS TO CRIMP PIERCING CONTACTS ON FLEXIBLE FLAT CABLES (FFC CABLES) FOR ELECTRONICS AND AUTOMOTIVE APPLICATIONS.

Machine Classification

Protection from electrical hazards, direct and indirect contacts

Class I ■
Class II ❑
Internal electrical power supply ❑

Type B ■
Type BF ❑
Type CF ❑

Protection from penetration

IP 20

Safety in potentially explosive environments

Unsuitable ■

A 1.2 - IDENTIFICATION OF THE PERSON/DEPARTMENT RESPONSIBLE FOR RISK ANALYSIS.
– TECHNICAL DEPARTMENT MANAGER

A 1.3 – AUDIT INTERVAL: YEARLY

A 2.0- IDENTIFICATION OF QUALITY AND QUANTITY FEATURES

A 2.1 - USE OF THE MACHINE

*A 2.1.1 - **Intended machine user**: Unskilled labourer - First level operator*

*A 2.1.2 - **Qualification required for the user**: The user must be trained on how to correctly use the machine and on the hazards caused by damages to and removal of safety devices.*

General Information

Name	FFC BASE MACHINE
Intended use	CRIMPING MACHINE FOR FFC CABLE CONTACTS
Intended operating environment	LABORATORY

A 2.1.5 - Ambient conditions: - relative humidity: 30 ÷ 75%
- temperature: + 10 ÷ +35° C
- atmospheric pressure: 700 ÷ 1060 hPa

A 2.3 - MATERIALS AND/OR COMPONENTS BUILT IN OR USED IN THE MACHINE

A2.3.1 - List of critical materials/components (the following materials/components must be approved):

SAFETY DEVICES AND ELECTRICAL AND ELECTRONIC COMPONENTS (SEE TECHNICAL FILE).

A 2.4 - ENVIRONMENTAL IMPACT ON THE MACHINE

A 2.4.1 - Possible environmental impact which may affect safety.

	t_a (°C)	RH%	P (hPa)
Operating environment	10 ÷ 35	30 ÷ 75%	700 ÷ 1060
Transport environment	-20 ÷ 70	10 ÷ 100%	500 ÷ 1060
Storage environment	-20 ÷ 70	10 ÷ 100%	500 ÷ 1060

Power supply				
ELECTRICAL	230 VAC÷10%	50/60 HZ	2.5 A	600 VA
PNEUMATIC	6 BAR	5 L/MIN		

Types of substances discharged
NONE

A 2.5 – MACHINE IMPACT ON THE ENVIRONMENT

■ INTERFERENCES TO THE POWER MAINS ❒ HEATING
❒ DISCARGE OF TOXIC SUBSTANCES ■ EMC INTERFERENCE GENERATOR

A 2.6 – CONSUMABLES AND/OR ESSENTIAL ACCESSORIES
Not applicable

A 2.7 – MAINTENANCE AND/OR CALIBRATION

A 2.7.1 - Parts subject to maintenance: As shown in the user manual.
A 2.7.2 - Maintenance interval and person in charge:
MAINTENANCE TO BE CARRIED OUT: See manual, by:
❒ USER/OPERATOR ■ MAINTENANCE ENGINEER

A 2.7.3 - How to monitor accuracy and precision.
■ PERIODIC CALIBRATION to be carried out by:
❒ OPERATOR ■ SKILLED ENGINEER
❒ SELF-CHECK ■ MECHANICAL MAINTENANCE ENGINEER

A 2.8 - SOFTWARE

A 2.8.1 - Software installation, change or replacement
❒ USER/OPERATOR ■ SKILLED ENGINEER

A 2.8.2 - Software interaction with equipment safety
❒ HIGH ❒ AVERAGE ❒ LOW ■ NONE

A 2.9 - LIMITED LIFE: N.A

A.2.9.1 – Storage time reduction: N.A

A 2.10- DELAYED EFFECTS AND/OR DUE TO LONG PERIODS OF USE

A 2.10.1 - Ergonomic effects: N.A
A 2.10.2 - Cumulative effects: N.A

A 2.11 - MECHANICAL FORCES APPLIED TO THE MACHINE: N.A

A.2.11.1 - Details of parts and associated mechanical forces
A.2.11..2 - Monitoring mechanical forces: N.A

A 2.12 - MACHINE LIFE

A.2.12.1 - Factors affecting machine life

■ AGEING ❒ ENVIRONMENT ❒.....

A. 2.12.2 - Maximum life and settings to be monitored: N.A

A 2.12. – SAFE DISACTIVATION AND DISPOSAL

A.2.12.1 - Scrappage

■ DISPOSAL OF SCRAPPAGE ❒ DISPOSAL OF TOXIC MATERIAL
❒ DISPOSAL OF HAZARDOUS MATERIAL ❒ ANY RECYCLABLE MATERIAL
❒ DISPOSAL OF LIQUIDS

A 2.12.2 - Instructions for scrapping the machine.

The user must comply with current local legislation. Our machine does not generate hazardous waste or waste requiring special treatment.

A 2.13. - TRAINING AND INSTALLATION:

A 2.13.1 - Training required for the user:

Having carefully read the User Manual

Staff involved: Operator – Mechanical maintenance engineer - Electrical maintenance engineer - Safety officer

A 2.13.2 - Installation

A 2.13.3 - Qualification required for machine installer: Mechanical-electrical maintenance engineer

A 2.13.4 - Training required for machine installer: Reading and understanding the instructions provided in the User Manual

A 2.13.5- Installation supervised by the manufacturer: If required

A 2.13.6 - Final testing/start-up (list of tests to be carried out): Not required

A 2.14.0– USER INTERFACE

A 2.14.0.1 – Critical human intervention

■ ACCESS TO MACHINE IS RESERVED TO AUTHORISED PEOPLE BY MEANS OF:
❒ KEY-OPERATED SWITCH ■PASSWORD (only for machine settings)
❒ BIOMETRIC RECOGNITION ■ AVAILABILITY OF SIGNAGE
❒ ALARM NOISE LEVEL
■ NORMALISED COLOUR CODING
❒ EXTERNAL DEVICES CONTROLLED FROM THE MAIN MENU:

A 2.14.1 – CONNECTIONS AND ACCESSORIES

■ POLARISED CONNECTIONS ■ LOCKED CONNECTIONS
■ FORCED CONNECTION INSERTION
■ DIFFERENT CONNECTORS FOR TYPE OF CONNECTION

A 2.14.2– CONTROL INTERFACE: N.A

A 2.14.3– DATA DISPLAY

■ IN THE USER LANGUAGE ■ ILLUMINATED DISPLAY
❒ TILTABLE DISPLAY ■ CLARITY OF INFORMATION

A 2.14.4– MENU

■ IN THE USER LANGUAGE ■ SELECTION CONTROL
■ TYPE OF NAVIGATION: *SEQUENTIAL*

A 2.15 - MACHINE TRANSPORT FEATURES

■ FIXED ❒ MOVING
❒ PORTABLE:
❒ WITH HANDLE ❒ ERGONOMICAL FEATURES FOR TRANSPORT
❒ WITH WHEELS ❒ WHEELS WITH BRAKES

❒ ANTI-ROLLOVER CARRIAG

B – TOXICOLOGICAL HAZARDS : N.A

C - IDENTIFICATION OF POSSIBLE HAZARDS

Key:

NA = Not Applicable
U.M. = User Manual

REF. NO.	HAZARD	NORMAL CONDITIONS	SINGLE FAULT CONDITION	NOTES
C1	***ENERGY***			
C1.1	Electricity	YES	YES	
C1.2	Heat	NO	YES	FAULTY MOTOR
C1.3	Ionising radiations	N.A		
C1.4	Non-ionising radiations	N.A		
C1.5	Visible radiations	N.A		
C1.6	Electromagnetic fields	YES	YES	
C1.7	Moving parts	N.A		
C1.8	Suspended weights	N.A		
C1.9	Patient's support machine fault	N.A		
C1.10	Pressure (container breakage)	N.A		
C1.11	Sound pressure	NO	NO	
C1.12	Vibration	NO	NO	
C1.13	Magnetic field (such as MRI)	NO	NO	
C2	***BIOLOGICAL***			
C2.1	Biological charge	N.A		
C2.2	Biological contamination	N.A		
C2.3	Biological incompatibility	N.A		
C2.4	Improper emission (substance/energy)	N.A		
C2.5	Toxicity	N.A		
C2.6	Infection (indirect)	N.A		
C2.7	Pirogenicity	N.A		
C2.8	Incapability to maintain safe hygiene levels	N.A		
C2.9	Degradation	N.A		
C3	***ENVIRONMENTAL HAZARDS AND CONTRIBUTING FACTORS***			
C3.1	Electromagnetic fields	YES	YES	
C3.2	Predisposition to electromagnetic interference	YES	YES	
C3.3	Emissions of electromagnetic interference	YES	YES	
C3.4	Unsuitable power supply	YES	YES	
C3.5	Unsuitable coolant source	NA		
C3.6	Storage or operation outside	YES		

REF. NO.	HAZARD	NORMAL CONDITIONS	SINGLE FAULT CONDITION	NOTES
	required ambient conditions			
C3.7	Incompatibility with other equipment to be used	NA		
C3.8	Accidental mechanical damage	NO	NO	
C3.9	Contamination caused by scrappage and/or machine disposal	NA		
C4	***HAZARDS CONNECTED WITH MACHINE USE***			
C4.1	Unsuitable labelling	NO		
C4.2	Inadequate user instructions	NO		
C4.3	Inadequate accessory specifications	NA		
C4.4	Inadequate specifications for preliminary checks	NO		
C4.5	Operating instructions excessively complex	NO		
C4.6	Unavailable or separate operating instructions	NO		
C4.7	Use by unskilled or untrained staff	YES		
C4.8	Reasonably predictable incorrect use	YES		
C4.9	Exposed sharp tips or corners etc.	YES	YES	
C5	***HAZARDS CAUSED BY FAILURE TO OPERATE, MISSED MAINTENANCE AND OBSOLESCENCE***			
C5.1	Unsuitable or missing maintenance specifications, including inadequate specifications for operating checks after a repair operation.	NO	NO	
C5.2	Lack of adequate estimate of machine life.	NO	NO	
C5.3	Loss of mechanical integrity	NO	NO	
C5.4	Unsuitable packaging (machine deterioration)	NO	NO	
C5.5	Improper reuse	YES		

D - RISK REDUCTION

Describe the means used to reduce any risk regarded as unacceptable to a minimum level in all stages of the process:

D1 - Direct safety devices (design)
D2 - Indirect safety devices (protection). Examples of protection are:
❒ REDUCED ACCESS (such as due to radiation hazard) -
■ PROTECTION FROM HAZARD (such as by means of a protective cover)

D3 - Redefinition of intended use

E - NEWLY ADDED HAZARDS

Establish and, if required, describe if the risk reduction procedure has introduced new hazards. N.A.

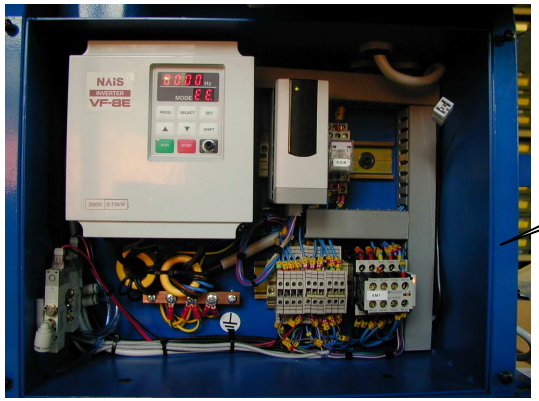
F - ASSESSMENT OF ALL IDENTIFIED HAZARDS

F1 - Risk assessment
Risks for all identified hazards
■ ESTIMATED
❒ NOT ESTIMATED

G - CONCLUSIONS

■ ALL POTENTIAL RISKS RELATED TO THE PRESCRIBED USE OF THE MACHINE HAVE BEEN ESTIMATED OR REMOVED.

❒ ALL POTENTIAL RISKS RELATED TO THE PRESCRIBED USE OF THE MACHINE HAVE BEEN ESTIMATED AND THE RESIDUAL RISKS, LISTED BELOW, ASSOCIATED TO IDENTIFIED HAZARDS, ARE ACCEPTABLE.



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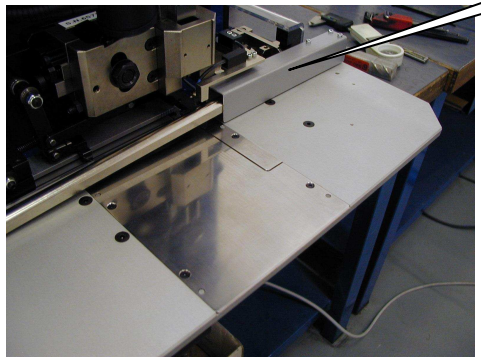

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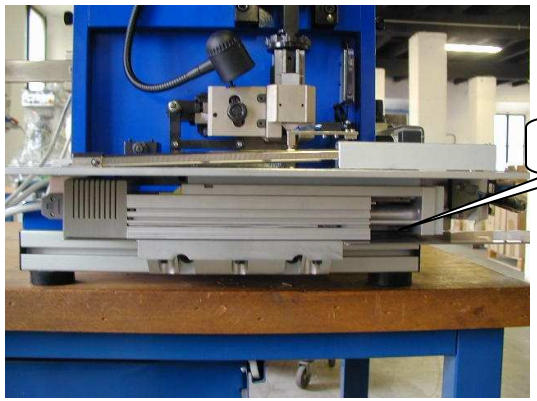

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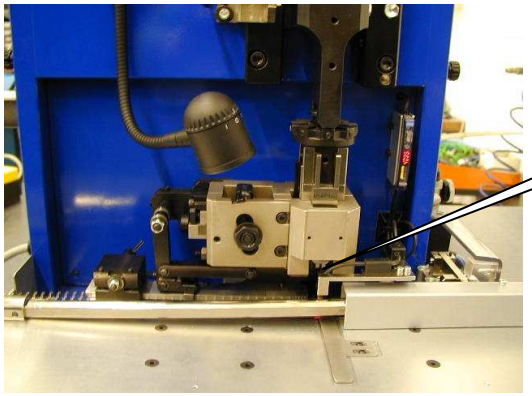

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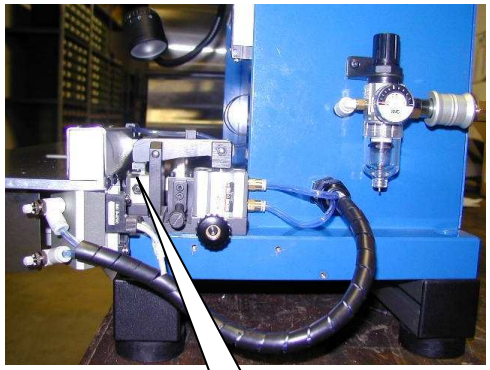

REF.8

H –

These are associated with a severity rate and a probability rate, as shown in the following table:

Probability **Severity**	**P1** (rare)	**P2** (infrequent)	**P3** (frequent)	**P4** (unavoidable)
G1 (irrelevant)	A	A	A	ALARP
S2 (slight)	A	A	ALARP	ALARP
S3 (slight)	A	ALARP	I	I
S4 (fatal)	ALARP	ALARP	I	I

the combination of both lead to the acceptability level, more specifically:

A = acceptable risk
ALARP = as low as reasonably practicable risk reduction
U = unacceptable risk
Irrelevant = Harm to people, things and animals which does not lead to injuries or damages
Slight= Harm to people, things or animals which has caused injuries/bruising likely to heal in a short period of time or slight damage
Serious= Harm to people, things or animals which caused injuries and serious permanent harm or damage
Fatal= Death of a person or an animal or irreparable/catastrophic damage to things

The technical solutions selected to reduce the risk must then be assessed, by making sure this operation has not introduced new hazards.
The investigation, i.e. continuing the risk assessment procedure, is carried out in compliance with applicable standards.
This leads to the following table:

					Risk reduction				
Nature or risk	Risk details	**P** (Probability)	**S** (Severity)	**P x S =A** (Acceptability)	**Solution**	**P** Probability	**S** Severity	**P x S =A** (Acceptability)	**Residual risk**
ENERGY RELATED HAZARDS									
Electricity (Ref.1 –2)	Electrocution by direct and indirect contact	2	4	**ALARP**	COMPLIANCE WITH STANDARD CEI EN60204-1 – FIXED GUARDS-LABELS	1	1	**A**	**A**
Heat	Not applicable	-	-	-		-	-	-	-
Ionising radiations	Not applicable	-	-	-		-	-	-	-
Non-ionising radiations (visible)	Not applicable	-	-	-		-	-	-	-
Electromagnetic fields	Emissions radiated by the machine	3	1	**A**	COMPLIANCE WITH STANDARDS EN5008-1 EN5008-2	1	1	**A**	**A**
Moving parts	Not applicable	-	-	-		-	-	-	-
Suspended weights	Not applicable	-	-	-		-	-	-	-
Springs	Not applicable	-	-	-		-	-	-	-

					Risk reduction				
Nature or risk	Risk details	**P** (Probability)	**S** (Severity)	**P x S =A** (Acceptability)	**Solution**	**P** Probability	**S** Severity	**P x S =A** (Acceptability)	**Residual risk**
Failure of a safety device	Injury to people	2	3	**ALARP**	Periodic inspections, staff training, notes in the U.M.	1	3	A	-
Removal of a safety device	Injury to people	2	3	**ALARP**	Periodic checks, staff training, notes in the U.M.	1	3	A	-
Removal of a safety switch	Injury to people	2	3	**ALARP**	Periodic inspections, staff training, notes in the U.M.	1	3	A	-
Pressure	Not applicable	-	-	-	-	-	-	-	-
Sound pressure	Not applicable	-	-	-	-	-	-	-	-
Vibrations	Not applicable	-	-	-	-	-	-	-	-
Magnetic fields	Electromagnetic fields generated by the machine	2	1	**A**	COMPLIANCE WITH STANDARD EN5008-1 EN5008-2	1	1	A	-
MECHANICAL HAZARDS									
Rotating parts (Ref.3)	Injury to people	3	2	ALARP	Moving guard	1	1	**A**	-
Moving parts (Ref.4)	Injury to people	3	2	ALARP	Moving guard	1	1	A	-
Cable blocking pneumatic clamp (Ref.5)	Slight bruising to fingers	3	1	A	Fixed guard	1	1	A	-
Electrical slide (Ref.6)	Slight bruising to fingers	1	2	A	Fixed guard	1	1	A	-
Crimping blades (Ref.7)	Bruising and wounding of tips of fingers.	2	2	ALARP	Moving guard	1	1	A	-

					Risk reduction				
Nature or risk	Risk details	**P** (Probability)	**S** (Severity)	**P x S =A** (Acceptability)	**Solution**	**P** Probability	**S** Severity	**P x S =A** (Acceptability)	**Residual risk**
Carrier cutting unit (Ref.8)	Bruising and wounding of tips of fingers.	2	2	ALARP	Fixed guard	1	1	A	-

					Risk reduction				
Nature or risk	Risk details	**P** (Probability)	**S** (Severity)	**P x S =A** (Acceptability)	**Solution**	**P** Probability	**S** Severity	**P x S =A** (Acceptability)	**Residual risk**
ENVIRONMENTAL AND BIOLOGICAL HAZARDS									
Electromagnetic interferences	Likelihood of emissions produced by other equipment	2	1	**A**	COMPLIANCE WITH STANDARD EN5008-1 EN5008-2	1	1	**A**	**A**
Unsuitable power supply	Not applicable	-	-	-		-	-	-	-
Probability of operation outside intended ambient conditions	Not applicable	-	-	-		-	-	-	-
Incompatibility with other machines/equipment	Not applicable	-	-	-		-	-	-	-
Biological hazards	Not applicable	-	-	-		-	-	-	-

					Risk reduction				
Nature or risk	Risk details	**P** (Probability)	**S** (Severity)	**P x S =A** (Acceptability)	**Solution**	**P** Probability	**S** Severity	**P x S =A** (Acceptability)	**Residual risk**
ERGONOMIC HAZARDS									
Exposed sharp corners	Injury to staff	3	2	**ALARP**	Notes on drawings and care of parts	1	1	**A**	**A**
Instability of machine	Rollover of machine	2	3	**ALARP**	notes in the U.M. - install the machine on a stable bench	1	3	A	A
Abrasive surfaces	Not applicable	-	-	-		-	-	-	-
Hot areas of the machine	Not applicable	-	-	-		-	-	-	-
Rotation of parts	Not applicable	-	-	-		-	-	-	-
Ejected parts	Not applicable	-	-	-		-	-	-	-

					Risk reduction				
Nature or risk	Risk details	**P** (Probability)	**S** (Severity)	**P x S =A** (Acceptability)	**Solution**	**P** Probability	**S** Severity	**P x S =A** (Acceptability)	**Residual risk**
HAZARDS CONNECTED WITH MACHINE USE									
Unsuitable labelling	All required information is missing	1	1	**A**	Inspection during the final testing stage	1	1	**A**	**A**
Unsuitable operating instructions	All required information is missing	1	1	**A**	Check the U.M.	1	1	**A**	**A**
Inadequate accessory specifications	Not applicable	-	-	-		-	-	-	-
Operating instructions excessively complex	Wrong installation and maintenance, not	1	1	**A**	Check the U.M.	1	1	**A**	**A**
Use by	Incorrect use of the	1	1	**A**	Cautions on U.M.	1	1	**A**	**A**

					Risk reduction				
Nature or risk	Risk details	**P** (Probability)	**S** (Severity)	**P x S =A** (Acceptability)	**Solution**	**P** Probability	**S** Severity	**P x S =A** (Acceptability)	**Residual risk**
unsuitable/inexperienced staff	machine and its accessories								
Reasonable predictable incorrect use	Not applicable	-	-	-		-	-	-	**A**
Incorrect measurement and other metrology issues	Not applicable	-	-	-	-	-	-	-	-
Incorrect transfer of data	Not applicable	-	-	-	-	-	-	-	-
Incorrectly presented data	Not applicable	-	-	-	-	-	-	-	-
HAZARDS CAUSED BY FUNCTIONAL FAULTS, MAINTENANCE AND AGEING									
Details of inadequate performance for intended use	Not applicable	-	-	-	-	-	-	-	-
Missing / unsuitable maintenance specifications, including inadequate specifications on functional inspections after maintenance operations	All required information is missing	1	1	**A**	Notes on the U.M.	1	1	**A**	**A**
Inadequate maintenance	Inefficient safety devices	1	3	**A**	Cautions on U.M.	1	1	**A**	**-**

6. ANY RESIDUAL RISKS

By issuing this document, the Management of COMTEC S.R.L declares to have taken into account and identified all hazards which could reasonably occur and associated risks have been assessed and reduced to an acceptable level.
The overall residual risk must be regarded as totally acceptable.

7. IS A NEW RISK ASSESSMENT REQUIRED?

No, unless new machine designs or applications are introduced.