

Appendix 1

Appendix 1

Doyen Product Details

The Doyen produces the most comprehensive range of medical device packaging equipment in the world. There are ten standard machine platforms within its five core product lines. Each machine is built in accordance to a standard design, however they can be customised to satisfy the unique packaging requirements of each customer application.

All machines are built to FDA, GMP, ISO, CE and other worldwide standards, and incorporate state-of-the-art electronic controls, servo motor drives and rapid changeover features.

Products manufactured in the UK

There are three products that are manufactured by Doyen Manufacturing Limited in the UK and marketed world-wide by the Doyen Group:-

The Four Side Seal machine (known as the 4SS). This is for packing medical device products into pouches that are subsequently sterilised at up to 250 packs per minute. There are two versions of the machine, the centre line and the datum edge. A twin lane version of this machine was developed and introduced in 1999. Most customers also require a small amount of customisation (such as changes to the length of the infeed, the colour of the machine, etc.). There are 40 of these machines in the field. This product is also manufactured in the USA.

The Four Side Seal machine has UK, Malaysian and US patents that were transferred from Datum Appropriate Technology as part of the acquisition in 1997. These patents were granted in 1993/94.

The Dressing Manufacturing System (Model DMS). This machine takes bulk material and converts it into individual dressings. Two types of dressings are manufactured: the strip dressing, and the island dressing (an island dressing has the absorbent pad surrounded by adhesive). The Dressing Manufacturing System normally has to be specially manufactured to comply with the customer's requirements. The machine usually comprises standard modules that are added to a special back plate. There are 8 of these machines in the field. The machine was significantly updated and redesigned during 1999 and 2000, and further enhanced for hydrogels in 2001.

Dressing Cutting System (Model PD120)

This is a simple dressing cutting system which takes bulk product, cuts and automatically places into the infeed of a 4SS or TR60 packaging machine. This is a new product and there are 7 units in the field. This product is also manufactured in the USA.

Products manufactured in the USA

The principal products that are manufactured in Doyen's Florida facility and marketed world wide by Doyen are :-

Continuous Motion Platen Four Side Seal Machine (Model HDW600 and HDW1200)

This is a high speed platen based machine that packs products into a four side seal style pack at up to 1200 products per minute. It is the fastest and most advanced machine in its class. This produces the same packs as the 4SS machine but is much higher speed and price. There are more than 50 units in the field.

Four Side Seal Packaging Machine (Model TR60)

This is a simple, entry level machine suitable for unsophisticated customers that will produce packed product at up to 120 packs per minute. Simple to operate and set up, there are more than 200 units in the field. Again it produces the same packs as the 4SS machine but is slower, cheaper and less flexible.

Transdermal Manufacturing Packaging System (Model TD600 and TD1200)

This machine is for the manufacture and packing of transdermal devices both in reservoir and monolith format. This is the fastest and most advanced machine in its field and will pack up to 1200 products per minute. There are 10 machines installed and in operation.

Surgeons' Glove Packing Machine

This machine automatically packs surgeons gloves in inner wallets for sterile use. This unit is normally linked to a four side seal machine such as the TR60, the 4SS machine or the HDW600/1200. There are more than 100 units in the field. The machine has been significantly upgraded in 1998 and 1999.

MT2500 Thermoforming Machines

Within the medical device market there are two principal methods of packing medical devices - the four side seal and the thermoforming or bubble pack machine. The thermoforming machine forms a pouch in the base web after which product is inserted into the pouch. Sealing and final cutting follows this operation. Doyen has delivered seven machines and a further 6 are being built against customer orders. This product is also manufactured in the UK. Doyen have a patent application for the toolless changeover of the MT2500. Initial searches in Europe have found no relevant prior art and a final decision to proceed with the patent will be required by October 2002.

Appendix 2

Appendix 2

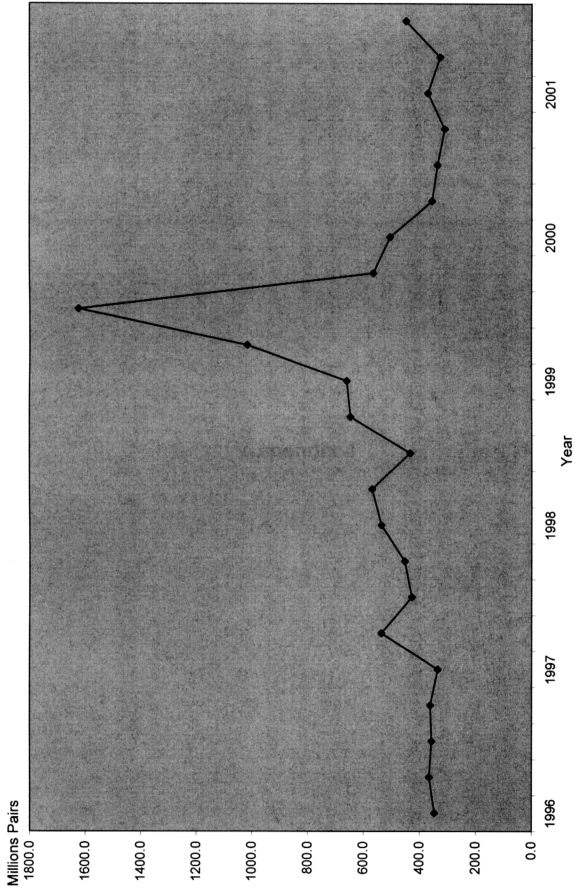
Doyen Gloves Packaging Machines Description

Doyen surgical gloves packing systems comprises of the following:

1. Inner wallet packaging machine, named as the Gloves Packaging Machines (GPM), with ability to pack up to 80 pairs of gloves per minute.
2. Outer pouch four sides seal machines, which can be any of the three four sides seal machines it manufactures:
 - i. High Speed Four Side Seal Packaging Machine (HDW), which uses the platen seal technology that has the ability to pack up to 120 pairs of gloves per minute.
 - ii. Quick Change Four Side Seal Packaging Machine (4SS) that uses rotary seal technology. Featuring quick and simple changeover for multiple product types, it has the ability to pack up to 150 pairs of gloves per minute (based on the improvement done in the latest R&D)
 - iii. TR60. A four side seal machine that uses rotary seal technology. Low in price but performance is low although comparable to competition machines. Not being market aggressively, only to the third world countries that cannot afford the price the other two machines mentioned above.
3. Automatic Glove Placing Machine, a new development recently that automatically places the gloves onto the travelling packaging material on the GPM. It is built to eliminates/reduce waste due to improper glove loading with more accurate glove placement and to reduce labour.

Appendix 3

Malaysia Surgical Gloves Export (1996 - 2001)



Appendix 4

Appendix 4

Costing Calculations

The costing is divided into three, capital investment, fixed operating costs and variable operating costs.

i. Capital Investment

Cost of Setting up ¹ :	RM 10,000.00
Cost of Packaging Machine ² :	RM 1,600,000.00
Cost of Clean Room Facilities ³ :	RM 200,000.00
Cost of Miscellaneous Equipment ⁴ :	RM 50,000.00
Total:	RM 1,860,000.00

ii. Fixed Operating Cost (per year)

Factory Rental ⁵	RM 30,000.00
Basic Overhead ⁶	RM 70,000.00
Machine Depreciation ⁷	RM 160,000.00
Facility Depreciation ⁸	RM 20,000.00
Misc. Equipment Depreciation ⁹	RM 5,000.00
Finance Charges ¹⁰	RM 167,400.00
Total:	RM 452,400.00

iii. Variable Operating Cost (per year)

Labour ¹¹	RM	239,600.00
Direct Overhead ¹²	RM	20,000.00
Utilities ¹³	RM	12,000.00
Maintenance ¹⁴	RM	4,400.00
Maintenance Components ¹⁵	RM	64,000.00

Total: **RM 340,000.00**

Total Operating Cost (per year): **RM 792,400.00**

iv. Other Cost ¹⁶

Tooling	RM	20,000.00
Validation per product	RM	60,000.00

Total: **RM 80,000.00**

Notes:

¹ including fees to ROC, fees for company secretarial services, etc.

² budgetary cost of a Doyen 4SS and a GPM

³ budgetary cost of setting up clean room facility based on estimated rates given in MIDA guide and the budgetary quotation obtained from a clean room constructor

⁴ Estimate of other equipment required such as air compressor, pallet jack, racking systems, basic tools, etc.

⁵ Factory rental is based on the survey done on the available factory lots in Kulim industrial area, at RM2500 per month

⁶ Basic overheads include the salary for permanent employees, insurance, basic utility expenses, housekeeping, etc.

Permanent Employees: 1 store clerk (RM1000), 1 machine operator (RM1200) & 2 security guards (2 x RM800). A factor of 1.3 is used to cater for the fringe benefits and annual salary is based on 13 months pay.

⁷ Machine depreciation is based on depreciate over 10 years

⁸ Facility depreciation is based on depreciate over 10 years

⁹ Misc. Equipment depreciation is based on depreciate over 10 years

¹⁰ Finance charges at 9% per annum

¹¹ Labour required for packaging works: 13 production operators

Production Operator is at RM8 per hour, based on 8 hours, 6 days week, 48 weeks

¹² Direct Overhead includes the maintenance of the facilities and the misc. equipment.

¹³ Utilities; Electrical is based on Tenaga Nasional Berhad tariff at 25.8 sen per kWh.

The estimate total kW is about 16 kW and operating hours per day is estimated at 10 hours per day. Based on 6 days a week, 48 weeks per year; total consumption per year is about 46,080kWh.

¹⁴ Maintenance of the machine is based on 10 days per annum using 2 Doyen local service personnel.

¹⁵ Components for the maintenance of machine is estimated on 4% per annum of the machine cost

¹⁶ Other cost incurred for additional tools and time taken for validation of the new products. These will be separately charged one time charge to the new clients and clients who wished to add new range of products.

Tooling is estimated to be RM 5000 per customer. No. tools is estimated to be 4 per year (2 for disaster recovery and 2 for standard contract pack).

Validation cost is approximately RM 3000 per product. Estimated no. of product per year is 20 (10 for disaster recovery and 10 for standard contract pack)

Assumption:

1. The total number of weeks per year is estimated to be 48 weeks.
2. The number of weeks sold is for calculations purposes only. The forecast total weeks sold is 36 weeks; 12 weeks for the disaster recovery in which 8 weeks are invoked/utilised. The standard contract pack contributes 24 weeks.

3. For disaster recovery, the clients will be sold a number of weeks, which are chargeable based on the fixed operating cost plus margin. If the clients utilised the facility, another charge will be incurred based on the variable operating cost plus margin.
4. A 3-shifts option is calculated by multiplying the variable operating cost by 3.
5. For calculations purposes, profit margins are proposed at 40% for the standard contract pack and 60% for the disaster recovery.

Appendix 4A

Contract Packing Models (1 Shift)

Disaster recovery

Revenue and expenses for disaster recovery activity (Ringgit Malaysia)

	Weekly				Annual Projected		
	Cost	Set up	Charge	Margin	Revenue	Margin	Cost
Annual costs to set up:							
Factory Rental	30000						
Basic Overhead	70000						
Machine depreciation	160000						
Facility depreciation	20000						
Misc. Equip. depreciation	5000						
Finance charge	167400						
Total	452400						
Per week	9425		23563	14138	282750	169650	113100
Cost per customer							
Tooling	5000	5000			10000	5000	5000
Cost per product							
Validation	3000	3000			30000	15000	15000
Cost to invoke per week							
Labour	4992						
Direct overhead	417						
Utilities	250						
Maintenance	92						
Components	1333						
Total per week	7084	7084	17709	10626	141673	85004	56669
Totals	16509		41272	24763	464423	274654	189769

Average cost per pack 0.0535 0.1338

Assumptions:

Cost for clean room per module	200000	
Machine cost	1600000	
Misc. Equip. Cost	50000	
Depreciation	10	years
Finance charges	9%	
Tooling per customer	5000	
Validation per product	3000	
Labour per shift of 8 hours	13	people
Labour rate	8	per hour
Direct overhead	20000	
Utilities	230	per week
Maintenance per running year	10	Days
Maintenance Charges per day	220	per day per person
Components per running year	64000	
Available weeks per year	48	
Weeks sold per year	12	
Weeks invoked per year	8	
Tools/module/year	2	sets
Products/module/year	10	
Manufacturing Efficiency	70%	
Target Margin	60%	

Contract Packing Models (1 Shift)

Standard Contract packing

Revenue and expenses for standard contract packaging activity (Ringgit Malaysia)

	Weekly				Annual Projected		
	Cost	Set up	Charge	Margin	Revenue	Margin	Cost
Annual costs to set up:							
Factory Rental	30000						
Basic Overhead	70000						
Machine depreciation	160000						
Facility depreciation	20000						
Misc. Equip. depreciation	5000						
Finance charge	167400						
Total	452400						
Per week	9425		15708	6283	377000	150800	226200
Cost per customer							
Tooling	5000	5000			10000	5000	5000
Cost per product							
Validation	3000	3000			30000	15000	15000
Cost to invoice per week							
Labour	4992						
Direct overhead	417						
Utilities	250						
Maintenance	92						
Components	1333						
Total per week	7084	7084	11806	4722	283347	113339	170008
Totals	16509		27514	11006	700347	284139	416208

Average cost per pack 0.0535 0.0892

Assumptions:

Cost for clean room per module	200000	
Machine cost	1600000	
Misc. Equip. Cost	50000	
Depreciation	10	years
Finance charges	9%	
Tooling per customer	5000	
Validation per product	3000	
Labour per shift of 8 hours	13	people
Labour rate	8	per hour
Direct overhead	20000	
Utilities	230	per week
Maintenance per running year	10	Days
Maintenance Charges per day	220	per day per person
Components per running year	64000	
Available weeks per year	48	
Weeks sold per year	24	

Contract Packing Models (1 Shift)

Summary of Revenue and Expenses

Total revenue per module (Ringgit Malaysia)

	Revenue	Margin
Disaster	464423	274654
Normal	700347	284139
Total	1164770	558793

Based on
36 single shifts per year

Appendix 4B

Disaster recovery

		Weekly				Annual Projected		
		Cost	Set up	Charge	Margin	Revenue	Margin	Cost
Annual costs to set up:								
Factory Rental	30000							
Basic Overhead	70000							
Machine depreciation	160000							
Facility depreciation	20000							
Misc. Equip. depreciation	5000							
Finance charge	167400							
Total	452400							
Per week		9425		23563	14138	282750	169650	113100
Cost per customer								
Tooling	5000		5000			10000	5000	5000
Cost per product								
Validation	3000		3000			30000	15000	15000
Cost to invoice per week								
Labour	4992							
Direct overhead	417							
Utilities	250							
Maintenance	92							
Components	1333							
Total per weekn (3 shifts)	7084	21251		53128	31877	425020	255012	170008
Totals		30676		76690	46014	747770	444662	303108

Assumptions:

Cost for clean room per module	200000	
Machine cost	1600000	
Misc. Equip. Cost	50000	
Depreciation	10	years
Finance charges	9%	
Tooling per customer	5000	
Validation per product	3000	
Labour per shift of 8 hours	13	people
Labour rate	8	per hour
Direct overhead	20000	
Utilities	230	per week
Maintenance per running year	10	Days
Maintenance Charges per day	220	per day per person
Components per running year	64000	
Available weeks per year	48	
Weeks sold per year	12	
Weeks invoked per year	8	
Tools/module/year	2	sets
Products/module/year	10	
Manufacturing Efficiency	70%	
Target Margin	60%	

Contract Packing Models (3 Shifts)

Standard Contract packing

Revenue and expenses for standard contract packaging activity (Ringgit Malaysia)

		Weekly				Annual Projected		
		Cost	Set up	Charge	Margin	Revenue	Margin	Cost
Annual costs to set up:								
Factory Rental	30000							
Basic Overhead	70000							
Machine depreciation	160000							
Facility depreciation	20000							
Misc. Equip. depreciation	5000							
Finance charge	167400							
Total	452400							
Per week		9425		15708	6283	377000	150800	226200
Cost per customer								
Tooling	5000		5000			10000	5000	5000
Cost per product								
Validation	3000		3000			30000	15000	15000
Cost to invoice per week								
Labour	4992							
Direct overhead	417							
Utilities	250							
Maintenance	92							
Components	1333							
Total per week (3 shifts)	7084	21251		35418	14167	850040	340016	510024
Totals		30676		51127	20451	1267040	510816	756224

Average cost per pack 0.0331 0.0552

Assumptions:

Cost for clean room per module	200000	
Machine cost	1600000	
Misc. Equip. Cost	50000	
Depreciation	10	years
Finance charges	9%	
Tooling per customer	5000	
Validation per product	3000	
Labour per shift of 8 hours	13	people
Labour rate	8	per hour
Direct overhead	20000	
Utilities	230	per week
Maintenance per running year	10	Days
Maintenance Charges per day	220	per day per person
Components per running year	64000	
Available weeks per year	48	
Weeks sold per year	24	

Contract Packing Models (3 Shifts)

Summary of Revenue and Expenses

Total revenue per module (Ringgit Malaysia)

	Revenue	Margin
Disaster	747770	444662
Normal	1267040	510816
Total	2014810	955478

Based on
36 single shifts per year