

MEDICAL TECHNOLOGY AND PHYSICS, SIR CHARLES GAIRDNER HOSPITAL

Submission DR233 - Department of Medical
Technology and Physics - Sir Charles Gairdner
Hospital

Productivity Commission Issues Paper: Right to
Repair

July 2021

Background

Biomedical Engineering (BME) professionals are essential in developing and advancing the usage of medical devices in clinical services. Depending on their training and area of employment, the responsibilities of biomedical engineering professionals can include:

- research, development and design of devices
- ensuring the safety and effectiveness of devices and systems
- selection and procurement of medical equipment
- installation and commissioning
- integration with electronics medical records and other systems
- daily operations monitoring
- managing and undertaking maintenance and repairs on medical devices.
(World Health Organisation 2017, page 21)

Biomedical Engineers and Technicians are qualified staff, many have tertiary qualifications in their field and can also be in specialised fields within biomedical engineering such as mechanical instrumentation engineering, electronics engineering as well as computer science. BME professionals routinely update their knowledge through continuous education, attending certified manufacturers' technical training courses when available, and, reading service and technical reports and documentation.

Medical Technology and Physics

The Medical Technology and Physics Department (MTP) at Sir Charles Gairdner Hospital (SCGH) is responsible for the following services and resources:

- Med Tech Services
 - Bioelectronics Engineering
 - Biomechanical Engineering
- Radiopharmaceutical Production and Development Centre (RAPID)
- Medical Physics
- Visual Electrophysiology Clinic
- Australian Inherited Retinal Disease Registry and DNA Bank

Med Tech Services is one of the core areas within the Medical Technology and Physics Department. Med Tech Services incorporates two subdivisions specialising in Bioelectronic and Biomedical Engineering along with [project Development](#).

In the Med Tech Services division we provide support to biomedical equipment used in SCGH and other hospitals within the North Metropolitan Health Service (NMHS). Effective and efficient support is provided by Biomedical Engineers, Technical Officers and Technologists that have undertaken both manufacturer endorsed and in-house training.

All of our staff hold formal university or TAFE qualifications in Electronics or Mechanical Engineering, Science, Computing, or Anatomy and Physiology, as well as belonging to professional associations within the Biomedical Engineering community.

We are responsible for ensuring that supported medical devices are maintained to manufacturers' specifications through:

- Routine quality assurance testing
- Electrical safety testing
- Repairs by qualified staff

Medical Technology and Physics (MTP) response

In regards to the Productivity Commission Issues Paper on the "Right to Repair"; MTP strongly recommend the **inclusion of medical technology equipment** in the scope of the inquiry.

Excluding medical technology from this paper could further what has already been increasingly occurring in the medical device industry over the last decade or longer where manufacturers and agents are monopolising and controlling the medical device industry and this has become costly and wasteful. The same issues and principles specified in the Right to Repair Issues Paper apply to medical equipment, however with impact on the cost and therefore accessibility of healthcare. Whilst MTP agree there are arguments for and against the inclusion of medical equipment in this inquiry, MTP consider the significant impact on rising public and private healthcare costs and healthcare accessibility compelling. Furthermore, MTP considers the inclusion of medical equipment in this enquiry to be in the best interest for Australians for the following reasons:

- Health accounts for a significant proportion of both the Commonwealth and State expenditure. In 2019/20 the Australian government spent \$87 billion (15% of expenditure) on health and in 2020/21 the WA government spent \$9,649 million (29% of expenditure) (Parliament of Australia 2021, Government of Western Australia 2021).
- Maintenance and repairs of much medical equipment in our public hospitals is done by technically trained professionals in the industry (and has historically been the case for many decades). In-house provided repairs and maintenance poses no greater risk to patients and staff than those made through manufacturer support.
- All risks are managed by quality control systems in place. SCGH MTP for instance are ISO9001:2015 certified as are many other BME departments. BMEs work to and comply to the common standards used in the industry including AS IEC 60601:2015, AS2500:2020, AS3551:2012, AS3003:201, AS 14971:2020, AS4187:2014. Provided staff are adequately trained, the risks are no greater and in many instances may actually be lower as there is greater oversight and transparency of medical equipment management and performance.
- Compliance with the Australian Standards requires the repair of medical equipment as per manufacturer specifications, unless a risk assessment is made. This necessitates the provision of all technical and service documentation when equipment is purchased. In-house BMEs are on-site and able to attend to equipment within minutes to diagnose and repair problems. With adequate parts and technical documentation the downtime of equipment is greatly reduced. This is particularly important for critical care equipment.

- e-waste is potentially reduced by having biomedical engineers service and maintain medical devices, as life expectancy of the equipment is extended when well maintained and serviced through its functional life.
 - Clearly manufacturers have a vested interest in replacing rather than repairing medical equipment as:
 - it increases the income stream and revenue for the company
 - less maintenance is required as it is not in service long enough to see reasonable wear and tear, minimising costs in delivering service contracts
- Some specialised medical equipment does not have local manufacturer support in Western Australia. This has proven to be problematic during covid restrictions, where some repairs and maintenance was reliant on interstate providers. Having in-house staff trained and certified to provide that support would overcome that issue and undoubtedly reduce the cost of support.

Major hospital BME departments are asking to have the choice to have repairs and maintenance for medical equipment either provided by the manufacturer or to be performed in-house with adequate training.

There are some circumstances where it is beneficial for the manufacturer to provide maintenance, service or repairs, including when:

- there is not the necessary infrastructure and tools required to perform work on the equipment
- no staff are qualified to perform the work
- there are insufficient staffing to take on such work
- the equipment is highly specialised and very niche in nature (MRI, CT and other imaging equipment)
- it is not cost-effective to provide the service

Where it is more cost effective and in the best interest of patients and healthcare staff, MTP would like the right to repair and maintain equipment.

Responses to information requests

INFORMATION REQUEST 1

What would a 'right to repair' entail in an Australian context? How should it be defined?

Medical equipment should be included within the definition of equipment with a "right to repair", due to its high cost value to the Australian and State governments and high risks for timely cost effective repairs. The "right to repair" would include the right to perform routine maintenance, performance evaluation and service in addition to repairs.

All unreasonable barriers created by manufacturers to restrict or limit third party qualified service personnel to support medical devices be removed for all equipment including medical equipment. This would include:

- Manufacturers to be transparent (within reason) with the technology, its design and service details and documentation, to the extent third party support can be provided.
- all parts of the devices specified and to be available for purchase at a cost effective price to either qualified individuals or business groups/entities to allow correct repair of the device.
- Require that staff/persons undertaking such repairs have been suitably trained or have formal qualifications in the field of expertise. This could require manufacturers' support in such training.

The Australian Standards for the repair and maintenance of medical equipment, including but not limited to AS/NZS IEC 60601:2015, AS3551:2012, AS ISO 14971:2020, AS2500:2020,AS3003:2018, include recommendations to follow manufacturers' requirements for preventative maintenance, repairs and testing or otherwise perform a risk assessment. Complying with these Australian Standards ensures the safety and quality of third party servicing, maintenance and repairs of medical equipment.

INFORMATION REQUEST 2

a) What types of products and repair markets should the Commission focus on?

This inquiry should include, but not be limited to, all Electronic, Mechanical and or Mechatronic devices including medical equipment.

b) Are there common characteristics that these products share (such as embedded technology and software or a high/low degree of product durability), and which characteristics would allow policy issues to be considered more broadly?

It is difficult to define the common characteristics of medical equipment and devices as they are very broad in their design and use, however in modern technology inclusive of both specialised medical equipment and consumer equipment, there is a high use of embedded technology and proprietary software. In many instances the proprietary software is installed on top of general consumer software, for instance the use of Microsoft Windows 7 or 10 etc.

c) If there are particular products that the Commission should focus on, what are the unique issues in those product repair markets that support such a focus?

Special focus should be provided in the area of medical equipment due to the extremely high cost of medical equipment and environmental impact on disposal of obsolete medical equipment. Electronics is well known to be very reliable especially in new semiconductor designs. Many circuits if designed in accordance of the properties and specifications of the parts used can last for many years beyond its economic end of life date. This is especially true when well maintained and serviced by qualified personnel with the correct tools and service documentation outside of the manufacturers service agencies. Manufacturers will only provide support to their devices for a limited amount of time, at which point the replacement of the device is required which is costly and wasteful, when the device potentially has many years of useful service life remaining. The increasing barriers in the "Right to Repair" medical equipment became more evident and problematic with the onset of the COVID-19 pandemic. The urgent need to repair critical equipment and to ensure equipment that had been in storage (some of which had been decommissioned) was fully functional, fit for purpose and in compliance with the applicable standards has been recognised around the world (He et al 2021, Svensson-Hoglund et al 2021).

INFORMATION REQUEST 3

a) Do the consumer guarantees under the ACL provide adequate access to repair remedies for defective goods? If not, what changes could be made to improve access to repair remedies? Are there barriers to repairing products purchased using new forms of payment technologies, such as ‘buy now pay later’?

Unable to comment

b) Is the guarantee of available repair facilities and spare parts effective in providing access to repair services and parts? Or is the opt out clause being widely used, making the guarantee ineffective?

In the medical device industry, there are no guarantees of available repair facilities and spare parts. Some authorised repair facilities are located in other countries, and these manufacturers will not supply the required spare parts, thus making the repair:

- i. More costly in comparison to the part required in many instances.
- ii. Increased downtime of the device.
 1. Manufacturers are aware of this so counteract this by either loaning out a replacement device that costs a significant amount of money; or by recommending entering a service contract or extended warranty agreement which in many cases does not represent value for money, and again goes against the right to repair philosophy.

c) Should consumer guarantees seek to balance the broader societal costs of remedy choices (such as the environmental impacts of replacements) with consumer rights, and if so how? For example, should repairs be favoured as a remedy?

Many tons of medical equipment is disposed of by hospital Biomedical Engineering departments every year, the environmental impact of this I would imagine would be undesirable. Biomedical Engineers in many instances undertake repairs to equipment as well as routine maintenance to extend the useful life far beyond the manufacturers expected life of the device.

d) Are consumers sufficiently aware of the remedies that are available to them, including the option to repair faulty products, under the ACL’s consumer guarantees?

- **If not, would more information and education be a cost effective measure to assist consumers understand and enforce guarantees? What would be the best way to deliver this information? What other measures would be more effective?**

Unable to comment

INFORMATION REQUEST 4

a) The Commission is seeking information on the nature of repair markets in Australia, including detailed data on the repair markets for specific products, covering:

- **market size — by employment, revenue, number of businesses, profit margins**
- **market composition — such as market share between authorised, independent and DIY repairers.**

Biomedical Engineering is a very niche market in the medical equipment service and repair industry. In comparison to many other service and repair centres its fairly small, however the nature of the work undertaken is critical, and all the devices are used to either treat or diagnose patients, some being life supporting devices such as ventilators that became a priority during the Covid pandemic.

- a. The industry is split by**
- i. The OEM's specific service centres.**
 - ii. Private companies set up as Biomedical engineering services, which also work as independent Medical equipment repair centres as well as align and become authorised repair centres for brands.**
 - iii. Privately owned Biomedical Engineering service centres.**
 - iv. Government run Biomedical Engineering departments that are usually housed within major tertiary hospitals.**

b) Is there any evidence of a difference in quality, safety or data security between authorised repair networks and independent repairers? Are there ways to address concerns around quality, safety or data security while promoting a vibrant independent repair market?

While it could be argued that Government run Biomedical engineering departments can and do take much pride and care in the work done, and in most cases do the work equivalent or better than OEM service centres as there are no profit margins or income bonuses to do the work, the incentive is always for the safety of patients and staff, we are next to front line workers all day every day, we see what happens, we see the use of the equipment, we see the implications of equipment failures. There is always the second part of the argument, where though potentially lack of education, knowledge, experience and documentation the work carried out may not be to the required professional standard. This is not isolated to the repair and service industry itself and may be seen in other professions as well as authorised and independent repairers.

c) Are there available examples of the contracts between OEMs and authorised repairers? Do these contracts limit effective competition in repair markets (such as by limiting the number and reach of authorised repairers or requiring authorised repairers to not be authorised by a competing brand)?

- **What is the process to become authorised? Is it open and competitive?**

In the Medical service industry it is known that OEM contracts exist with authorised repairers. Many of these contracts limit effective competition as service and technical information is limited to a specific manufacturer authorised

repair centre. In the medical equipment repair industry generally there may only be 1 nationally or 1 looking after many states. To become authorised a manufacturer certified biomedical engineer training course needs to be completed and all the correct tools purchased.

d) Are there specific examples or other evidence of practices by OEMs or their authorised repairers that create barriers to competition in repair markets?

- **Do other factors also create barriers to competition in repair markets, such as short sighted consumer behaviours, switching costs, poor information availability or consumer lock in?**

Please note company and staff have been anonymised for privacy in this example.

In this example, the OEM company XXXX in 2014 were able to sell the original output connector at a cost price of \$26 (*see Attachment 1*). The replacement of this part is a fairly simple process for technically trained and competent staff irrespective of manufacturer training. The example shows a routine quality assurance (QA) check of the device work order raised by the BME management database 04/07/2014. The unit was sent to BME department on the 24th, the connector was found to be faulty, replaced and a QA and functional test passed, work completed and returned to clinical service the same day.

In 2017 the same company changed its parts supply policy as can be seen in the text excerpt from OEM service agency stating they now do not supply replacement parts. The unit under the new manufacturer policy has a fixed repair cost \$850 and will need to be sent to the manufacturer overseas (*see Attachment 2 for email chain*). The item had the same issue with a broken output connector; it was then required to be sent out to OEM for repair, with a repair turnaround time of just over 2 months! (*see Attachment 3 for work order record*).

e) What is the relationship between the intensity of competition in the primary product market and the risk of consumer harm from a lack of competition in repair markets? Can competitive primary markets compensate for non competitive repair markets?

- **Is an absence of effective competition in the primary market a necessary condition for consumer harm from non competitive repair markets?**
- **To what extent would measures that enhance competition in the primary market address concerns about a lack of competition in repair markets?**

From my knowledge there is little effective competition in the Biomedical engineering repair market, it's a specialised niche service industry again also restricted by OEM's.

f) Are the restrictive trade practices provisions of the CCA (such as the provisions on misuse of market power, exclusive dealing or anti-competitive contracts) sufficient to deal with any anti competitive behaviours in repair markets?

Unable to comment

g) What policy changes could be introduced if there is a need to increase competition in repair markets and improve consumer access to, and affordability of, repairs?

- **What are the costs and benefits of any such proposal to the community as a whole? How does it balance the rights of manufacturers and suppliers, with those of consumers and repairers?**

A policy that would mandate on the sale of every major medical device and specific minor devices to public hospitals, manufacturer certified engineer training and service documentation is included in the purchase price irrespective of any further service and maintenance contract agreement. This would allow the service entity to decide the best outcome of service and maintenance requirements.

INFORMATION REQUEST 5

a) To what extent do current IP laws already facilitate repairs by consumers or independent third parties (e.g. the spare parts defence under the Design Act)?

IP laws are there for good reason, and yes should be respected for their purpose. However it does create significant challenges to independent third party repair and service entities. In the Medical equipment space propriety designs in hardware and software are not released beyond the manufacturing headquarters. This can be limiting to creativity and further developments in the Biomedical engineering community.

b) Are there any aspects of IP laws where consumers' rights with respect to repairs are uncertain?

Unable to comment

c) Do current IP protections (e.g. intellectual property rights, technological protection measures, end user licencing agreements) pose a significant barrier to repair in Australia? If yes, please comment on any or all of the following:

- **the specific IP protections that prevent consumers from sourcing competitive repairs and/or inhibit competition in repair markets**
- **the types of products or repair markets these barriers mainly affect**
- **the prevalence of these barriers**
- **the impacts of these barriers on third party repairers and consumers (e.g. financial cost, poorer quality repairs)**
- **options for reducing these barriers and their associated benefits, costs and risks (including potential impact on market offerings).**

IP protections can and do in many instances create barriers in the service and repair industry. Specifically in the Medical equipment repair industry, most of

the technical information of the systems are not released by the manufacturers e.g. Schematic diagrams, software of the system, deep level diagnostic software etc. In some instances manufacturers will provide at a cost to the service agency Certified technical training. This in many instances only goes to a technical level to undertake general routine maintenance of the device and basic level repairs and parts replacement. In the instances when Biomedical Engineers are not able to repair or service the device due to lack of detailed service documentation or parts, it becomes a financial and time cost to have the devices sent out for repair, it becomes less effective with the logistics process that occurs to send equipment out for repair.

d) In what ways might government facilitate legal access to embedded software in consumer and other goods for the purpose of repairs? What are the pros and cons of these approaches?

The government could facilitate for the manufacturers to become more transparent with software and firmware in their systems. This would make it easier to diagnose, repair and update the systems. Although In medical devices there would be no reason nor would it be safe to disassemble embedded software of medical devices for clinical use. However for study, education and research purposes and to encourage creativity in the Biomedical engineering field this would be of great benefit.

INFORMATION REQUEST 6

a) What evidence is there of planned obsolescence in Australian product markets? Do concerns about planned obsolescence principally relate to premature failure of devices or in them being discarded still working when more attractive products enter the market?

Planned obsolescence is very evident in the medical device industry. Medical technology moves at a fast rate, although it has historically been behind the pace in many respects in comparison to general consumer technology. This is due to more stringent testing requirements, research and development, safety and reliability issues and approval processes, as many of these devices are used to protect and save lives. We see many times manufactures or sales agencies working on behalf of manufacturers recommending the replacement of medical equipment on the basis that the new equipment has new features. In many if not most instances the equipment in use still functions as its intended prime purpose. We also see many systems needing to be prematurely decommissioned because the next revision of firmware has been released and the manufacture no longer provides either technical support or parts for the current system, even though again it is still maintainable and functional in its current state. Medical equipment is significantly more costly in comparison to general consumer products, as such when such systems are replaced it comes as a major expense to public purse. It's always nice to have the latest phone, latest piece of technology for a few nice extra features but this is at a cost to society and the environment.

b) How can the Commission distinguish between planned product obsolescence and the natural evolution of products due to technological change and consumer demand?

Obsolescence should not occur when the device still achieves its primary function. Nor should it occur as a result of software implications. There will be times though when the software has developed to such a point that the hardware is not able to cope with the resource demand of the software. It could also be a choice provided to the consumer to only have features in software that would be of use or benefit to the end user.

c) How does planned obsolescence affect repairers, consumers and the broader community in Australia?

The cost for planned obsolescence in the medical industry costs the state and federal budgets significant amounts every year. There is also a significant cost to the environment due to the amount of e-waste created. A growing trend in the medical device industry is to have certain pieces of equipment or items used once and then disposed of.. It is acceptable, however in some instances for highly infectious patients where medical grade cleaning is not effective enough and a high risk of patient or staff contamination may occur..

d) What measures do governments currently use to prevent planned obsolescence or mitigate its effects (in Australia and overseas)? How effective are these measures?

Unable to comment?

e) What are the benefits, costs and risks of Australia adopting measures similar to those currently used overseas, such as product design standards and reparability ratings?

It would be an advantage to the consumer to have a reparability rating on equipment as it gives the consumer a choice; as well it may influence medical equipment tenders and contracts.

f) Do consumers have access to good information about durability and reparability when making purchases? If not, how could access to information be improved?

We don't think there is good formal information regarding the durability and reparability about equipment; however with the internet and online forums and blogs there is information spread among the public regarding certain equipment reliability, durability, reparability. Magazine issues like **choice** may help influence when making purchases, but you would need to pay for a subscription for this information. The Government could make a free online peered review of specifications, reliability and reparability of equipment.

INFORMATION REQUEST 7

a) What data are available on the amount of e waste generated in Australia?

- **What data is there on the composition of e waste in terms of particular materials (such as hazardous materials) by product type?**
- **How does hazardous e waste compare to hazardous general waste in its prevalence and risks? Is there merit in distinguishing between hazardous e waste and non hazardous e waste? And if so, how could this be done in practice?**

We are not aware of any formal data available on the amount of e-waste generated in Australia, (it might be available). In respect to the disposal of medical equipment there would be anecdotal evidence than many tons of equipment is disposed of every year.

b) What estimates are available on the costs of e waste disposal on the environment, human health and social amenity, in Australia and internationally?

- **How do the impacts differ by disposal type, or by the type of product or hazardous material?**

Unable to comment

c) How much of Australia's e waste is shipped overseas for recycling? Is there evidence of circumstances where this creates problems for recipient countries?

- **Are there barriers to the expansion of domestic recycling facilities or the adoption of new recycling technologies in Australia (such as plasma arc incinerators)?**

Unable to comment

d) What are Australia's current policy settings for managing the potential environmental and health effects of e waste (such as landfill bans, the National Television and Computer Recycling Scheme or Mobile Muster)? Are these policy settings broadly right — that is, are they proportional to the impacts of e waste on the community?

Unable to comment

e) How can a right to repair policy further reduce the net costs of e waste in Australia, and would such an approach be an effective and efficient means of addressing the costs of e waste to the community?

With a right to repair policy, especially in the medical device industry equipment would have a much longer and useful life. This would in turn reduce the amount of e-waste, and be favourable in the economic budgets. With all of this there would need to be some controlled risk inherited in the process of the health department.

INFORMATION REQUEST 8

a) What policy reforms or suite of policies (if any) are necessary to facilitate a 'right to repair' in Australia?

Unable to comment

b) Are there any other barriers to repair and/or policy responses that the Commission should consider?

In the medical device industry, Legal responsibilities and Risks.

c) What are the costs and the benefits of the various policy responses that have been proposed to facilitate repair (such as those outlined in table 1)?

Unable to comment

d) Are there other international policy measures or proposals that the Commission should consider as part of this inquiry?

Unable to comment

References

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Parliament of Australia, Australian Government expenditure (2021), Available at: https://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/pubs/rp/BudgetReview202021/AustralianGovernmentExpenditure, (Accessed 12 July 2021).

Svensson-Hoglund S, Richter JL, Maitre-Ekern E, Russell JD, Pihlajarinne T, Dalhammar C, 2021, 'Barriers, enablers and market governance: A review of the policy landscape for repair of consumer electronics in the EU and the U.S.', *Journal of Cleaner Production*, vol 288, pp 1-18.

World Health Organisation (2017), Medical device technical series: Human resources for medical devices, the role of the biomedical engineers, Available at: <https://www.who.int/teams/health-product-and-policy-standards/assistive-and-medical-technology/medical-devices/human-resources> (Accessed 12 July 2021).

Attachment 1:

Available OEM Part (2014)

Work Order

Summary

Number S0006413

Requestor ██████████

Fault Scheduled QA

Expected Completion 01/08/2014

Total Cost \$26

[Edit Cost](#)

Account Chargeable

Completed 24/07/2014

Item Details

Item [00002199](#)

Owner Department Ward ██████████

Hospital ██████████
Hospital

WO Details

Date and Time	Description	Hours
04/07/2014 01:30:35	Work Order Requested	
24/07/2014 09:16:42	QA Started	
24/07/2014 09:44:31	Replaced Parts - Output connector	
24/07/2014 09:47:49	QA Passed	
24/07/2014 09:48:02	Work Order Completed	

Attachment 2:

OEM Part no longer available (2017) – Email Chain

From: XXXXXXXXXXX

Sent: Thursday, 14 September 2017 4:18 PM

To: XXXXXXXXXXX

Subject: Servicing 5392

Hi XXXXXX,

I have pasted what I received back from Sydney office.

XXXXXXXXXXXXXX

Sales Supervisor- IBHRE/NASPExAM

Western Australia | CRHF

Company XXXXX

XXXXXXXX Australasia Pty Ltd

XXXXXXXX | Facebook | LinkedIn | Twitter | YouTube

LET'S TAKE HEALTHCARE

FURTHER, TOGETHER

Hi XXXXXX,

We have a set repair price of \$850+GST inclusive of full repair and service and a PM price of \$250+GST where we perform the checkout test on the EPG.

Kind Regards,


Attachment 3:

OEM Part no longer available (2017) – Work Order Record

Work Order

Summary

Number V0011615

Requestor 

Fault Atrial lead will no longer work after box was dropped on the floor.

Expected Completion 19/08/2017

Total Cost \$850

[Edit Cost](#)

Account Chargeable

Completed 03/01/2018

Item Details

Item [00022682](#)

Owner Department Operating Theatres

WO Details

Date and Time	Description
16/08/2017 09:13:24	Work Order Requested
29/09/2017 08:59:43	I tried to buy output connectors from agent.They won't sell connectors anymore.
29/09/2017 09:02:23	Request to Send Out
29/09/2017 09:02:43	Updated Time
05/10/2017 12:51:05	Item Sent Out on GA-005648
02/01/2018 13:19:10	Item Returned
03/01/2018 09:02:54	Work Order Completed